NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

July 14-15, 2021

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

Please do not remove the book from the meeting room.

Nevada State Board of Pharmacy

985 DAMONTE RANCH PARKWAY • SUITE 206 • RENO, NEVADA 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

Date Posted: June 29, 2021

AMENDED AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, July 14, 2021 at 9:00 am. The meeting will continue, if necessary, on Thursday, July 15, 2021 at 9:00 am or until the Board concludes its business at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

Please Note:

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

The Nevada State Board of Pharmacy may address agenda items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency or effectiveness of the meeting;

The Nevada State Board of Pharmacy may combine two or more agenda items for consideration; and

The Nevada State Board of Pharmacy may remove an item from the agenda or delay discussion relating to an item on the agenda at any time.

The Nevada State Board of Pharmacy may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of any of the below named parties.

Public comment is welcomed by the Board, but will be heard during the public comment item and may be limited to three minutes per person. You may call into the videoconference by

following the link or calling the phone number listed above. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

Public comment may also be submitted to the Board at pharmacy@pharmacy.nv.gov.

Prior to the commencement and conclusion of a contested case or a quasi judicial proceeding that may affect the due process rights of an individual the board may refuse to consider public comment. See NRS 233B.126. Please be aware that after the quasi-judicial board or commission has rendered a decision in the contested case and, assuming this happens before adjournment, the board or commission may entertain public comment on the proceeding at that time**.**

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

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

◈ CONSENT AGENDA ◈

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

3. Approval of the June 2-3, 2021 Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Pharmacy License (NRS 639.2328) – Non-appearance (**FOR POSSIBLE ACTION**)

A. A & M Pharmacy LLC – Orlando, FL
B. Adelaide Apothecary – Lexington, KY
C. Benecard Central Fill of FL, LLC – Bonita Springs, FL
D. BILH Pharmacy Direct – Westwood, MA
E. BILH Specialty Pharmacy – Westwood, MA
F. Care Fusion Rx – Garden Grove, CA
G. Colton Pharmacy – Colton, CA
H. Lifeline Specialty Pharmacy – Ellicott City, MD
I. Gretna Xpress Pharmacy – Terrytown, LA
J. Medpack LLC – Brooklyn, NY
K. Optum Pharmacy 701 – Flint, MI
L. ReCept Pharmacy #75 – El Paso, TX
M. Truax Patient Services, LLC – Bemidji, MN
N. US MED, LLC – Miami, FL
O. XeCare LLC – New Albany, OH

4.2 Application for Out-of-State Compounding Pharmacy License (NRS 639.2328) – Non-appearance **(FOR POSSIBLE ACTION)**

P. Crimson Valley Pharmacy, LLC – Saint George, UT
Q. Excel Pharmacy – Saint Peters, MO
R. MedQuickRx – Los Angeles, CA

4.3 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance (**FOR POSSIBLE ACTION**)

S. AZ Diabetic Supply Inc. – Vienna, VA
T. Care Airways Corp – Boca Raton, FL
U. CRI – Towson, MD
V. Curitec, LLC – New Smyrna Beach, FL
W. Maximum DME Corporation – Placentia, CA
X. Monitor Medical, Inc. – Sugar Land, TX
Y. Preferred Medical – Camphill, PA
Z. Preferred Medical – Conway, AR
AA. Preferred Medical – Jacksonville, FL
BB. Preferred Medical – Kansas City, KS
CC. Preferred Medical – Waco, TX
DD. Sleep Central – Murray, KY
EE. United States Medical Supply, LLC – Doral, FL
FF. US MED, LLC – Miami, FL
GG. Visible Supply Chain Management – West Jordan, UT
HH. Wolf Medical – Sunrise, FL

4.4 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Non-appearance (**FOR POSSIBLE ACTION**)

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

Background Check Not Required by Law.

4.5.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

4.5.2 Manufacturer (NAC 639.593(7)(d))

II. AMAG Pharmaceuticals, Inc. – Waltham, MA
JJ. Avadel CNS Pharmaceuticals, LLC – Chesterfield, MO
KK. Corium, Inc. – Grand Rapids, MI
LL. Covis Pharma US, Inc. – King of Prussia, PA
MM. Darmerica, LLC – Casselberry, FL
NN. Glenmark Therapeutics Inc. USA – Mahwah, NJ
OO. Horizon Therapeutics USA, Inc. – Deerfield, IL
PP. Juno Therapeutics Inc. – Bothell, WA
QQ. Landmark Supply, Inc. – Highland Park, NJ
RR. Nostrum Laboratories, Inc. – Kansas City, MO

SS. TechLab, Inc. – Radford, VA

4.5.3 Publicly Traded (NAC 639.593(7)(a))

4.5.4 VAWD-Accredited (NAC 639.593(7)(c))

TT. Owens & Minor Distribution, Inc. – Ontario, CA
UU. SRCL Expert Solutions LLC – Indianapolis, IN

4.5.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

Cardinal Health 200, LLC – Riverside, CA

4.5.5 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

VV. Amicus Therapeutics US, LLC – Philadelphia, PA
WW. APL Sales I LLC – Waltham, MA
XX. Applied Therapeutics, Inc. – Englewood Cliffs, NJ
YY. Celgene Corporation – Summit, NJ
ZZ. Dexcom, Inc. – San Diego, CA
AAA. G1 Therapeutics, Inc. – Research Triangle Park, NC
BBB. Helius Medical, Inc – Newtown, PA
CCC. Novavax, Inc. – Gaithersburg, MD
DDD. Parcus Medical, LLC – Sarasota, FL
EEE. Pharming Healthcare, Inc. – Warren, NJ
FFF. Tetraphase Pharmaceuticals, Inc. – Waltham, MA

4.5.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

4.5.7 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

GGG. Organon LLC – Kenilworth, NJ

4.6 Application for Nevada Wholesaler License (NRS 639.233) – Non-appearance **(FOR POSSIBLE ACTION)**

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

HHH. Silver State Drug – Alamo – Alamo, NV

◈ REGULAR AGENDA ◈

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

A. Aurora Bejto, RPH (21-021-RPH-N)
B. Direct Compounding and Outsourcing, LLC (19-070-PH-S)

C. Scot Silber, RPH (19-070-RPH-S)
D. Michael Thomas, PT (19-070-PT-A-S)
E. Krystal Hernandez, PT (19-070-PT-B-S)
F. Richard Jensen, RPH (21-036-RPH-A-N)
G. Jerry Potmesil, RPH (21-036-RPH-B-N)
H. Flying Diamond Pharmacy, LLC (21-036-PH-N)
I. Steven Klomp, MD (19-265-CS-N)
J. Sassan Kaveh, MD (21-051-CS-N)
K. Jill Oliver, MD (20-007-PD-S)
L. Karen Arcotta, MD (21-046-CS-S)
M. Jeff Chen, MD (20-001-CS-N)

6. Applications for Pharmaceutical Technician in Training Registration (NAC 639.242) – Appearance. (**FOR POSSIBLE ACTION)**

A. Aaron Borecki
B. Lisa Fuentes
C. Odetta Kilgore
D. Barbara Piedra
E. Clinton Rickman
F. Julie Sonekeo
G. David Tilsen

7. Applications for Pharmaceutical Technician Registration (NAC 639.240) – Appearance. (**FOR POSSIBLE ACTION)**

A. Lizbeth Lara
B. Antonio Madrid

8. Applications for Advance Practice Registered Nurse – Prescribe Registration (NAC 639.850) – Appearance. (**FOR POSSIBLE ACTION)**

A. Lindsay McComas
B. Aubree Teribury

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

A. Cure 4 The Kids Foundation Patient Pharmacy – Las Vegas, NV
B. Elemental Pharmacy – Las Vegas, NV
C. Elite Medical Center, an extension of Valley Hospital Pharmacy – Las Vegas, NV
D. Genoa Healthcare, LLC – Las Vegas
E. The Desert Hope Center – Las Vegas, NV
F. The Medicine Shoppe Retail Pharmacy – Las Vegas, NV

10. Application for Nevada Compounding Pharmacy License (NRS 639.230)

– Appearance (**FOR POSSIBLE ACTION**)

The Medicine Shoppe LTC Pharmacy – Las Vegas, NV

11. Applications for Out-of-State Pharmacy License (NRS 639.2328) – Appearance

    A. Ed Snell's Pharmacy Shop & Oxygen – Pocatello, ID
    B. Marley Drug, Inc. – Winston-Salem, NC
    C. MedWiseRx – Austin, TX
    D. Pyramids Infusion Center – Webster, TX
    E. UCSD Home Infusion Pharmacy

12. Applications for Out-of-State Compounding Pharmacy License (NRS 639.2328) – Appearance (**FOR POSSIBLE ACTION**)

    A. Northmark Pharmacy – Cincinnati, OH
    B. Soleo Health Inc. – Dublin, OH

13. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6942) – Appearance (**FOR POSSIBLE ACTION**)

    A. Cranial Technologies, Inc. – Las Vegas, NV
    B. Patients Choice, LLC – North Las Vegas, NV

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

    A. Biologic, LLC – Las Vegas, NV – Background Check completed in compliance with NRS 639.500 – Disqualifying Events - Disclosure
    B. Dia-foot – Las Vegas, NV - Background Check completed in compliance with NRS 639.500 –No Disqualifying Events

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

    A. Amsino Medical, Inc. – Aurora, IL – Background Check Not Required – Manufacturer (NAC 639.593(7)(d)) – Disclosure
    B. Crown Laboratories – Johnson City, TN – Background Check Not Required - Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d) - Disclosure
    C. Solaris Pharma Corporation – Bridgewater, NJ – Background Check completed in compliance with NRS 639.500 – No Disqualifying Events

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

    A. Empower Pharmacy – Houston, TX
    B. Exela Pharma Sciences, LLC – Lenoir, NC

17. Request for waiver from managing pharmacist pursuant to NRS 639.220 (3)

    Kodilichi Izuora

18. Request for Approval of Change of Managing Pharmacist pursuant to NRS 639.220 **(FOR POSSIBLE ACTION)**

Pharmerica Reno

19. Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Appearance **(FOR POSSIBLE ACTION)**

Danielle Plummer

20. Application for Pharmacist Registration by Examination – Appearance (**FOR POSSIBLE ACTION**)

    Adam Katschke

21. Application for Pharmacy Registration by Reciprocation – Appearance (**FOR POSSIBLE ACTION**)

    Armin Aryan

22. Report from Michael Hillerby, Kaempfer Crowell, on 81st Session (2021) of Nevada Legislature.

23. Discussion and possible action on proposal to conduct future Board meetings at a physical location with public access, while 1) permitting members of the general public the option of attending via remote technology; 2) permitting applicants for licensure or renewal the option of appearing on their application via remote technology; and 3) requiring parties and witnesses in contested cases to appear in-person. (**FOR POSSIBLE ACTION**)

24. Approval of revised Pharmacy License Application **(FOR POSSIBLE ACTION)**

25. Approval of new Ambulatory Surgical Center and Recovery Center License Application **(FOR POSSIBLE ACTION)**

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

27. Executive Secretary Report:

    A. Financial Report
    B. Issuance of Temporary Licenses and Registrations

C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. COVID-19 Response
F. Licensing Software Update
G. Licensing Activities Report
H. PMP Integration

◈ WORKSHOP ◈

Thursday July 15, 2021 – 9:00 am

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

A. **Amendment of Nevada Administrative Code (NAC) Chapter 639.** The proposed amendment will implement the provisions of Senate Bill 408 requiring an applicant for registration as a pharmacist, pharmaceutical technician or pharmaceutical technician in training to undergo a criminal background check; increase the fees for the investigation or issuance or renewal of a license as a manufacturer or wholesaler; provide that an application for any certificate, license or permit issued by the Board is only valid for 1 year after the date it is received by the Board unless the Board extends its period of validity, and clarify the licensing requirements for an outsourcing facility or euthanasia technician.

B. **Amendment of Nevada Administrative Code (NAC) 453.510: Schedule I**. The proposed amendment to NAC 453.510 will add Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine) and fentanyl related substances (Fentanyl Carbamate (Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate); Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl); N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl); Fluoroacryl fentanyl; Fluoro furanyl fentanyl; Methyl acetyl fentanyl); Phenylpropanoyl fentanyl; Fluorobutyryl fentanyl); Phenyl fentanyl (some trade or other names: benzoyl fentanyl); Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl).
to the list of controlled substances listed in Schedule I.

C. **Amendment of Nevada Administrative Code (NAC) 453.540: Schedule IV**. The proposed amendment to NAC 453.540 will add lemborexant and remimazolam, to the list of controlled substances listed in Schedule IV.

D. **Amendment of Nevada Administrative Code (NAC 639).** The proposed amendments will add a new section to implement the provisions of Senate Bill 190, requiring the Board to adopt regulations that establish a protocol to allow a pharmacist to dispense a self-administered hormonal contraceptive to any patient.

E. **Amendment of Nevada Administrative Code (NAC 639.)** The proposed amendments will create a new section to implement the provisions of Senate Bill 325 requiring the Board to adopt regulations that establish requirements to allow a pharmacist to dispense drugs approved by the United States Food and Drug Administration for preventing the acquisition of human immunodeficiency virus.

29. Date and Location of Next Scheduled Board Meeting:

September 1-2, 2021 – Las Vegas, NV

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

31. Adjournment

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

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

No Continuing Education credit, will be given for attending this Board meeting.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

1

2

3

MINUTES

June 2-3, 2021

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, June 2, 2021 at 9:00 am. The meeting will continue, if necessary, on Thursday, June 3, 2021 at 9:00 am or until the Board concludes its business at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

Board Members Present:

Helen Park	Jade Jacobo	Krystal Freitas	Gener Tejero
Wayne Mitchell	Rolf Zakariassen	Richard Tomasso	

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Courtney Lee
Brett Kandt	Joe Dodge	Dena McClish	Kristopher Mangosing
Sophia Long	Ken Scheuber	Darlene Nases	Luis Curras
Leo Basch			

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

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Governor's directive and Open Meeting Laws for Nevada.

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

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

2. Public Comment June 2, 2021, 9:00 AM

Sheyanne Moore stated that she was in attendance to appear regarding her application.

Steve Syracuse stated that he was in attendance to appear regarding his application.

3. Approval of the April 14-15, 2021 Meeting Minutes

Board Action:

Motion: Jade Jacobo moved to approve the April 14-15, 2021 Meeting Minutes.

Second: Wayne Mitchell

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Pharmacy License – Non-appearance (**FOR POSSIBLE ACTION**)

A. Bandana Rx – Concord, CA
B. Cherry Hill Village Pharmacy LLC – Canton, MI
C. HighPoint Pharmacy – Arlington, TX
D. J & B Pharmacy Services Inc. – Wixom, MI
E. Manifest Pharmacy – Greer, SC
F. NIXONA RX LLC – Phoenix, AZ
G. Optum Frontier Therapies, LLC – Flint, MI
H. Pyramids Infusion Center – Webster, TX
I. Telecare Pharmacy LLC – Libertyville, IL
J. Tin RX Castro San Francisco – San Francisco, CA

4.2 Application for Out-of-State Compounding Pharmacy License – Non-appearance (**FOR POSSIBLE ACTION**)

K. Beaker Pharmacy – McKinney, TX
L. Riverside Pharmacy – Bullhead City, AZ
M. The Daily Dose Pharmacy – Austin, TX

4.3 Applications for Out-of-State Medical, Devices, Equipment and Gases License – Non-appearance (**FOR POSSIBLE ACTION**)

N. Agiliti Health, Inc – McDonough, GA
O. Agiliti Health, Inc. – Memphis, TN
P. Agiliti Health, Inc – Norcross, GA
Q. Agiliti Health, Inc – Salt Lake City, UT
R. American Medical Distribution, Inc. – Largo, FL
S. ASMR LLC – Centennial, CO
T. BioTel INR, LLC – South San Francisco, CA
U. Calmed Medical Supplies and Repair, Inc. – Southfield, MI
V. CardioNet, LLC – Malvern, PA
W. CardioNet, LLC – San Francisco, CA
X. Cerotto Inc. – Riverside, CA
Y. DDP Medical Supply – St. Petersburg, FL
Z. Developed Medical, LLC – Manalapan, NJ
AA. DEXCOM, INC – Mesa, AZ
BB. Gaboro Medical Supply – Stroudsburg, PA
CC. Henry Schein Inc. – Fort Worth, TX
DD. Home Delivery Incontinent Supplies. Co. – St. Peters, MO
EE. Horizon Medical Solutions, Inc. – Norwood, MA
FF. LifeSure LLC – Miramar, FL
GG. Lincoln Health Supply – Fort Lauderdale, FL
HH. MED-EL Corporation – Durham, NC
II. Pathema DME LLC – Lauderhill, FL
JJ. Tarheel Surgical Supply, LLC – Thomasville, NC
KK. Telcare Medical Supply, LLC – Linwood, PA
LL. The Medcom Group, Ltd. – Windsor, CO
MM. West Lake Rx, LLC – San Antonio, TX
NN. Wound Care Resources, Inc. – Yorkville, TN
OO. Wound Care Resources Sales - Yorkville, TN

4.4 Applications for Nevada Medical, Devices, Equipment and Gases License – Non-appearance (**FOR POSSIBLE ACTION**)

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

Background Check Not Required by Law.

4.5.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

4.5.2 Manufacturer (NAC 639.593(7)(d))

PP. Accord BioPharma Inc – Durham, NC
QQ. Accord Healthcare Inc – Durham, NC
RR. Anivive Lifesciences, Inc. – Lakewood, CA
SS. Apollo Pharmaceuticals USA Inc. – Palm Beach Gardens, FL
TT. Athem, LLC – East Brunswick, NJ

UU. Blu Pharmaceuticals – Greenvale, NY
VV. BTG International Inc. – West Conshohocken, PA
WW. Distribution Unlimited LLC – Peoria, AZ
XX. Horizon Medicines LLC – Deerfield, IL
YY. Mayne Pharma, Inc. – Greenville, NC
ZZ. Nomax Inc./Amcon Laboratories Inc. – St.Louis, MO
AAA. Oryza Pharmaceuticals, Inc. – Coral Springs, FL
BBB. Primary Pharmaceuticals, INC – Ocean Springs, MS
CCC. Tanvex BioPharma USA, Inc. – San Diego, CA

4.5.3 Publicly Traded (NAC 639.593(7)(a))

4.5.4 VAWD-Accredited (NAC 639.593(7)(c))

DDD. DDP Medical Supply, St. Petersburg, FL
EEE. MXR Imaging Inc. – Hazelwood, MO
FFF. Optum Frontier Therapies, LLC – Flint, MI
GGG. UPS Supply Chain Solutions, Inc. – Columbus, OH

4.5.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

4.5.5 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

HHH. ADC Therapeutics America, Inc. – Murray Hill, NJ
III. Akcea Therapeutics, Inc. – Boston, MA
JJJ. Ardelyx, Inc. – Waltham, MA
KKK. Dicerna Pharmaceuticals, Inc. – Lexington, MA
LLL. Oyster Point Pharma, Inc. – Princeton, NJ
MMM. Palatin Technologies, Inc. – Cranbury, NJ
NNN. Radius Health, Inc. – Boston, MA
OOO. Teligent Pharma, Inc. – Buena, NJ
PPP. Viela Bio, Inc. – Gaithersburg, MD
QQQ. Y-mAbs Therapeutics, Inc. – Nutley, NJ

4.5.6 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

RRR. McKesson Medical-Surgical Inc. – City of Industry, CA
SSS. McKesson Medical-Surgical Inc. – Jacksonville, FL
TTT. McKesson Medical-Surgical Inc. – Stoughton, MA
UUU. UPS Supply Chain Solutions, Inc. – Harrisburg, PA

4.5.7 **Background checks completed in compliance with NRS 639.500. No Disqualifying Events.**

VVV. Dynamic Diagnostics, Inc. – Plymouth, MI
WWW. Fresenius Kabi, LLC – Pleasant Prairie, WI

XXX. Nexus Pharmaceuticals Inc. – Lincolnshire, IL
YYY. Redwood Distribution – El Paso, TX
ZZZ. Right Way Medical, LLC – Westerville, OH

4.6 Application for Nevada Wholesaler License – Non-appearance **(FOR POSSIBLE ACTION)**

4.6.1 Manufacturer (NAC 639.593(7)(d))

AAAA. Intra-Sana Laboratories LLC – Las Vegas, NV

4.7 Application for Nevada Warehouse License– Non-appearance **(FOR POSSIBLE ACTION)**

BBBB. Optum Frontier Therapies II, LLC – Las Vegas, NV

The Board discussed the products and services provided by item 4H and requested staff remove item from the Consent Agenda and have the company appear at a future Board meeting.

Jade Jacobo recused from participation for items G, FF, and BBBB since she works for the company.

Board Action:

Motion: Wayne Mitchell moved to approve Consent Agenda items 4G, 4FF, and 4BBBB.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo recused).

Board Action:

Motion: Wayne Mitchell moved to approve the Consent Agenda except items 4G, 4FF, 4BBBB, and 4H.

Second: Richard Tomasso

Action: Passed unanimously.

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

A. Vidur Mahadeva, MD (20-111-CS-N)

Carl Hebert appeared as counsel representing Dr. Mahadeva.

Dr. Mahadeva appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt prosecuted the case and referenced the documents entered into the record by stipulation of the parties, including the initial suspension of Dr. Mahadeva's DEA registration, the subsequent suspension of his Registration No. CS11174, the November 17, 2020, search of his office and seizure of his inventory of controlled substances and dangerous drugs, and his subsequent execution of the DEA Surrender for Cause.

Mr. Hebert called Dr. Mahadeva as a witness; Dr. Mahadeva testified concerning his practices with regard to drugs and answered questions from the Board.

Board discussion ensued regarding the other people involved at his practice and their role, how he obtained some of his drugs, why did he not throw out his expired/adulterated drugs, and if he was prescribing and dispensing drugs without a valid registration.

Mr. Kandt requested that the Board make findings of fact consistent with paragraphs 1-11 of the First Amended Accusation with the removal of the specific date mentioned in paragraph 8.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to make findings of fact as proposed by Mr. Kandt.

Second: Wayne Mitchell

Action: Passed unanimously.

Mr. Kandt requested that the Board make conclusions of law consistent with paragraphs 12-29 of the First Amended Accusation which includes six causes of action.

Board Action:

Motion: Wayne Mitchell moved to make conclusions of law as proposed by Mr. Kandt.

Second: Rolf Zakariassen

Action: Passed unanimously.

Mr. Kandt requested that President Park enter his timesheet for prosecuting this matter into the record. The total amount for attorney's fees and costs was $1989.10. Mr. Hebert had no objection.

President Park admitted the timesheet into the record.

Mr. Kandt requested that the Board revoke Dr. Mahadeva's Certificate of Registration No. CS11174. Dr. Mahadeva may petition for reinstatement after one year with revocation effective immediately. Dr. Mahadeva to pay $10000 fine.

Richard Tomasso commented that Dr. Mahadeva may petition for reinstatement after two years is more appropriate.

Board Action:

Motion: Richard Tomasso moved to revoke Dr. Mahadeva's Certificate of Registration No. CS11174 effective immediately. Dr. Mahadeva may not petition for reinstatement for two years, and shall pay a fine of $10000.

Second: Wayne Mitchell

Action: Passed unanimously.

Mr. Kandt requested that the Board award $1989.10 in attorney's fees and costs pursuant to NRS 622.400 on the basis that they were reasonable, necessary and actually incurred.

Mr. Hebert commented that he reviewed the attorney's fees and costs and finds it reasonable.

Board Action:

Motion: Jade Jacobo moved to award attorney's fees and costs of $1989.10 pursuant to NRS 622.400 as proposed by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

B. Frank Silver, MD (21-001-CS-S)

Robert DeMarco appeared as counsel representing Dr. Silver.

Dr. Silver was not present.

Gener Tejero disclosed that he knows Dr. Silver but stated that he could participate in this matter fairly and without bias.

Brett Kandt prosecuted the case and presented a proposed a Stipulation and Order for the Board's consideration.

1. Respondent pay a fine of $3000 payable to the State of Nevada
2. Respondent pay $1000 for recoverable attorney's fees and costs to the Nevada State Board of Pharmacy
3. Respondent shall establish policies and procedures in his practice to ensure compliance with Nevada law.
4. Respondent shall comply with all federal and state statutes and regulations regarding cosmetic injectables.

Board discussion ensued.

Mr. DeMarco had no objections to the Stipulation and Order presented by Mr. Kandt.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order as presented by Mr. Kandt regarding Case No. 21-001-CS-S.

Second: Wayne Mitchell

Action: Passed unanimously.

C. Lin's Supermarket, Inc. (18-028-PH-S) (20-063-PH-S)

This matter was continued to a future Board Meeting.

D. Katila Pipitone, RPH (18-028-RPH-A-S) (20-063-RPH-S)

This matter was continued to a future Board Meeting.

E. Timothy Johnson, RPH (18-028-RPH-B-S)

This matter was continued to a future Board Meeting.

F. Direct Compounding and Outsourcing, LLC (19-070-PH-S)

This matter was continued to a future Board Meeting.

G. Scot Silber, RPH (19-070-RPH-S)

This matter was continued to a future Board Meeting.

H. Michael Thomas, PT (19-070-PT-A-S)

This matter was continued to a future Board Meeting.

I. Krystal Hernandez, PT (19-070-PT-B-S)

This matter was continued to a future Board Meeting.

J. Gary Manley, PA-C (20-224-CS-S)

Todd Weiss appeared as counsel representing Mr. Manley.

Mr. Manley was not present.

President Park disclosed that she worked with Mr. Manley but stated that she could participate in this matter fairly and without bias.

Krystal Freitas disclosed that she was a student of Mr. Manley but stated that she could participate in this matter fairly and without bias.

Brett Kandt prosecuted the case and referenced the Order to Show Cause issued in response to Mr. Manley's surrender of his DEA registration for cause.

Board discussion ensued.

Mr. Kandt requested that the Board make findings of fact consistent with paragraphs 1-4 of the Order to Show Cause.

Board Action:

Motion: Wayne Mitchell moved to make findings of fact as proposed by Mr. Kandt.

Second: Rolf Zakariassen

Action: Passed unanimously.

Mr. Kandt requested that the Board make conclusions of law consistent with paragraph 5 in the Order of Show Cause.

Board Action:

Motion: Jade Jacobo moved to make conclusions of law as proposed by Mr. Kandt.

Second: President Park

Action: Passed unanimously.

Mr. Kandt requested that the Board revoke Mr. Manley's Certificate of Registration No. CS18989. Mr. Manley may petition for reinstatement after one year with revocation effective immediately.

Board Action:

Motion: Jade Jacobo moved to revoke Mr. Manley's Certificate of Registration No. CS18989. Mr. Manley may petition for reinstatement after one year with revocation effective immediately.

Second: Rolf Zakariassen

Action: Passed unanimously.

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

A. SleepSafeSolutions LLC (20-131-S)

SleepSafeSolutions LLC withdrew their appeal.

Mr. Kandt requested that a letter by the respondent be entered into the record requesting withdrawal of their appeal.

President Park entered the letter into the record.

B. Rafael Mirchou, MD (19-107-S)

Mr. Kandt stated that the respondent vacated their appeal.

Mr. Kandt requested that a letter by the respondent be entered into the record requesting withdrawal of his appeal.

President Park entered the letter into the record.

22. Application for Euthanasia Technician Registration– Appearance. (**FOR POSSIBLE ACTION)**

Christina Lee Pope-Madziarek

Christina Lee Pope-Madziarek appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Pope-Madziarek provided background on her disclosure regarding an arrest for possession of an illegal substance. She commented that she has changed.

Board discussion ensued regarding the process of providing the euthanasia service, what type of euthanasia drugs would be used, and if she still has a problem with substance abuse.

Ms. Pope-Madziarek answered questions to the Board's satisfaction.

Board discussion ensued regarding putting conditions on her licensure.

Board Action:

Motion: Jade Jacobo moved to approve Christina Lee Pope-Madziarek's Euthanasia Technician application with the condition that she can only administer Sodium Pentobarbital.

Second: Gener Tejero

Action: Passed unanimously.

9. Applications for Pharmaceutical Technician in Training Registration– Appearance. (**FOR POSSIBLE ACTION)**

C. Sheyanne Moore

Sheyanne Moore appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Moore provided background on her disclosure regarding illegal substance abuse. She commented that she has changed.

Board discussion ensued regarding her disclosure, if her counseling is personal or subject by a court order, and if the Managing Pharmacist who signed her application still works at the pharmacy.

Ms. Moore answered questions to the Board's satisfaction.

Board discussion ensued regarding Ms. Moore undergoing a PRN evaluation or equivalent.

Board Action:

Motion: Jade Jacobo moved to approve Sheyanne Moore's Pharmaceutical Technician in Training registration pending favorable PRN evaluation or equivalent.

Second: Krystal Freitas

Action: Passed unanimously.

13. Application for Nevada Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

A. Elemental Pharmacy – Las Vegas, NV

Randy Case, CEO, and Jenner Sinang, Managing Pharmacist, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Case provided background on the application and his disclosure regarding a DUI.

Joe Dodge, Nevada Board of Pharmacy Inspector, questioned Mr. Case and Mr. Sinang regarding the business model and Mr. Sinang's work history.

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

Board discussion ensued regarding concerns of Mr. Case recommending his hemp business to customers. In addition, Mr. Sinang's work history is not properly reflected in the application.

President Park offered Mr. Case the opportunity to table his application in order to get the correct information regarding Mr. Sinang's work history.

President Park tabled Elemental Pharmacy's application at their request.

D. Premier Pharmacy – Las Vegas, NV

Johnny Nguyen, Owner, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge questioned Mr. Nguyen regarding his business model and their Managing Pharmacist, Jorge Ramirez-Silva's, work history.

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

Board Action:

Motion: Jade Jacobo moved to approve Premier Pharmacy license.

Second: Wayne Mitchell

Action: Passed unanimously.

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

G. VET4U, LLC – East Syracuse, NY – Background Check completed in compliance with NRS 639.500 – Disqualifying Events – Disclosure

Raymond Davis, Owner, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Davis provided background on his disclosure regarding a DUI and the business model for his company.

Board Action:

Motion: Wayne Mitchell moved to approve Out of State Wholesaler license for Vet4U, LLC.

Second: Gener Tejero

Action: Passed unanimously.

8. Application for Recovery Center License- Appearance **(FOR POSSIBLE ACTION)**

Desert Orthopaedic Center Recovery Center – Las Vegas, NV

Mary Grear (Managing Pharmacist), Mike Rose (Administrator), and Derek Goffstein (Medical Director) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Kandt provided background on their appearance as this is the first application for this license category.

President Park disclosed that Ms. Grear is on the Board of Trustees at Roseman University but stated that she could participate in this matter fairly and without bias.

Board questioned Ms. Grear regarding the company's business model, her administrative disclosure, and company's procedure for unlabeled medicine.

Ms. Grear answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve Recovery Center license for Desert Orthopaedic Center Recovery Center.

Second: Gener Tejero

Action: Passed unanimously.

9. Applications for Pharmaceutical Technician in Training Registration– Appearance. (**FOR POSSIBLE ACTION)**

A. Nicole Brooks

Nicole Brooks appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Brooks requested a closed session for this matter.

Board Action:

Motion: President Park moved to go into closed session for Nicole Brooks.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: President Park moved to go into open session.

Second: Jade Jacobo

Action: Passed unanimously.

No decision was made regarding Ms. Brooks application during closed session.

President Park questioned Ms. Brooks on why she wants to be a pharmacy technician.

Ms. Brooks answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve Nicole Brooks Pharmaceutical Technician in Training registration pending updated application to reflect her disclosure.

Second: Jade Jacobo

Action: Passed unanimously.

B. Odetta Kilgore

Odetta Kilgore appeared and was sworn in by President Park prior to answering questions and offering testimony.

Courtney Lee, General Counsel for Nevada State Board of Pharmacy, provided background on Ms. Kilgore's disclosures.

Board discussion ensued regarding clarification on Ms. Kilgore's disclosures and events that occurred with it, and wanted to know how Ms. Kilgore has changed since then.

Ms. Kilgore answered questions from the Board, but she was unable to provide an explanation for the revocation of her driver's license.

Board Action:

Motion: Jade Jacobo moved to deny Odetta Kilgore's Pharmaceutical Technician in Training registration.

Second: Wayne Mitchell

President Park commented that she would consider giving Ms. Kilgore another chance.

Gener Tejero commented that he would need more information before deciding on her application.

Aye: Jacobo
Nay: Park, Mitchell, Zakariassen, Freitas, Tomasso, Tejero

Action: Motion fails.

President Park offered Ms. Kilgore the opportunity to table her application in order to retrieve the information regarding her revocation of driver's license for the Board to review.

President Park tabled Ms. Kilgore's application at her request.

D. Jodi Sabala

Jodi Sabala appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Sabala stated that she changed her last name back to her maiden name. She goes by Jodi Sills.

Ms. Sills presented a letter of recommendation to the Board by her Managing Pharmacist.

Ms. Lee provided background to the Board regarding Ms. Sills disclosure regarding stolen property.

Board wanted clarification on events that occurred with her disclosure and how she changed since then.

Ms. Sills answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve Jodi Sills Pharmaceutical Technician in Training registration.

Second: Krystal Freitas

Action: Passed unanimously.

10. Applications for Intern Pharmacist Registration– Appearance. (**FOR POSSIBLE ACTION)**

Ryan Kniesner

Ryan Kniesner appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background to Board regarding Mr. Kniesner's disclosures regarding a DUI, driving without privileges, alcoholic possession/consume/purchase by a minor, and a battery charge.

Board questioned Mr. Kniesner's current standing in school, why he decided to change since his disclosures, and if he still consumes alcohol.

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

Board Action:

Motion: Jade Jacobo moved to approve Ryan Kniesner's Intern Pharmacist registration pending favorable PRN evaluation or equivalent.

Second: Wayne Mitchell

Action: Passed unanimously.

11. Applications for Controlled Substance Registration - Appearance. (**FOR POSSIBLE ACTION)**

B. Chester Wright, MD

Chester Wright appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background on Mr. Wright's disclosure regarding alcohol addiction.

Mr. Wright commented that he is sober now.

Board questioned Mr. Wright on if he is in good standing in Montana and clarification of when he completed his treatment.

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

Board Action:

Motion: Gener Tejero moved to approve Chester Wright's Controlled Substance registration.

Second: Rolf Zakariassen

Action: Passed unanimously.

12. Applications for Advance Practice Registered Nurse – Prescribe Registration– Appearance. (**FOR POSSIBLE ACTION)**

Pippa Stewart

Pippa Stewart appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Kandt provided background to the Board on Ms. Stewart's disclosure.

Board questioned Ms. Stewart regarding her current license status in California and if her fines have been paid.

Ms. Stewart answered questions to the Board's satisfaction.

Board discussion ensured regarding Ms. Stewart's disclosure and possible restrictions to her Nevada license.

Board Action:

Motion: Jade Jacobo moved to approve Pippa Stewart's Advance Practice Registered Nurse – Prescribe registration with conditions to only allow dangerous drugs. If she would like to obtain a Controlled Substance registration, she will need to apply after one year and appear in front of the Board.

Second: Krystal Freitas

Aye: Park, Zakariassen, Freitas, Tomasso, Jacobo, Tejero
Nay: Mitchell

Action: Motion carries.

13. Application for Nevada Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

B. PipelineRx – Las Vegas, NV

Pamela Obah, Managing Pharmacist, and Christopher Smith, Legal Counsel, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background regarding an ownership change.

Mr. Dodge questioned Ms. Obah regarding the business model and their disclosure for PipelineRx.

Ms. Obah answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve change of ownership for PipelineRx Pharmacy license.

Second: Jade Jacobo

Action: Passed unanimously.

C. Plus One Pharmacy, LLC – Las Vegas, NV

David Shimp (Managing Pharmacist), Anisha Patel (Owner), and Sachan Patel (Pharmacy Consultant) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board regarding Mr. Shimp's disclosures.

Board questioned Mr. Shimp on if he appeared in front of the Board previously for his disclosures, what events occurred with his disclosure regarding reckless driving, and his work experience.

Board questioned Ms. Patel on what her role is and why she wanted to open a pharmacy.

Mr. Shimp and Ms. Patel answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve Plus One Pharmacy license.

Second: Krystal Freitas

Action: Passed unanimously.

14. Applications for Out-of-State Compounding Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

A. AlleReach Pharmacy – Dallas, TX

Erica Lager, Managing Pharmacist, and Jared Moss, Legal Counsel, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background regarding an ownership change.

President Park requested a letter of authorization for Ms. Lager to speak on behalf of the company.

Ms. Lager confirmed that she sent a letter of authorization to Board staff .

Board questioned Ms. Lager regarding the business model of the company and who they plan to ship products to in Nevada.

Ms. Lager answered questions to the Board's satisfaction.

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, commented that their business model needs to follow Nevada Law. He asked if they can change their business model to be compliant with the law.

Ms. Lager commented that she needs to discuss with her company.

President Park offered Ms. Lager the opportunity to table their application in order to see if the business model can change to follow Nevada Law.

President Park tabled AlleReach Pharmacy's application at their request.

B. Braun Pharma LLC – Chicago, IL

Alisa Wolbers, General Manager, and Sharron Seymour, Managing Pharmacist, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background regarding an ownership change.

Board questioned Ms. Seymour regarding the business model, if the company has any changes to their operations, and their process for sterile compounding.

Ms. Seymour answered questions to the Board's satisfaction.

<u>Board Action:</u>

Motion: Richard Tomasso moved to approve change of ownership for Braun Pharma LLC Out-of-State Compounding Pharmacy license.

Second: Jade Jacobo
Action: Passed unanimously.

C. Ed Snell's Pharmacy Shop & Oxygen – Pocatello, ID

Benjamin Snell, Owner, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background on application to the Board.

Mr. Dodge questioned Mr. Snell on the company's business model and their Managing Pharmacist, Toni Cantrell's, work history.

Mr. Snell commented that their Managing Pharmacist has changed to Cheyanne Nickerson.

Mr. Snell answered Board's questions, but he was unable to provide detailed information regarding Ms. Nickerson's work history.

Mr. Dodge suggested that Ms. Nickerson be present for this appearance.

Mr. Snell commented that Ms. Nickerson is out on vacation.

President Park offered Mr. Snell the opportunity to table their application in order for the Managing Pharmacist to be present.

President Park tabled Ed Snell's Pharmacy Shop & Oxygen application at their request.

D. Paragon Infusion Care, Inc. – Plano, TX

This matter was moved to 6/3/21.

E. Valor Compounding Pharmacy – Berkeley, CA

Ann Olaguer (Director of Business Initiatives), Christina Stephanos (Chief Pharmacy Officer), and Rick Niemi (CEO) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board regarding their disclosures.

Ms. Olaguer provided an explanation to the Board regarding her administrative action.

Mr. Dodge questioned Ms. Olaguer regarding their current license status in California, the status of their Washington administrative action, their business model, and the results of their California Board inspection.

Ms. Olaguer and Mr. Niemi answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve Valor Compounding Pharmacy Out-of-State Compounding Pharmacy license pending receipt of California Board inspection and final disposition for Case No. 6433.

Second: Krystal Freitas

Action: Passed unanimously.

11. Applications for Controlled Substance Registration - Appearance. (**FOR POSSIBLE ACTION)**

A. Hisbay Ali, MD

No representative on behalf of Mr. Ali was present.

7. Petition for Reinstatement of Pharmacy Technician Registration and Request to Appear Before the Board – Appearance. **(FOR POSSIBLE ACTION)**

Breana Clark

No representative on behalf of Ms. Clark was present.

Public Comment June 2, 2021, 5:00pm

There was no public comment.

Board Members Present:

Helen Park	Jade Jacobo	Krystal Freitas	Gener Tejero
Wayne Mitchell	Rolf Zakariassen	Richard Tomasso	

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Courtney Lee
Brett Kandt	Joe Dodge	Dena McClish	Kristopher Mangosing
Sophia Long	Ken Scheuber	Darlene Nases	Luis Curras
Leo Basch			

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

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Governor's directive and Open Meeting Laws for Nevada.

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment June 3, 2021, 9:00 AM

There was no public comment.

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

Amendment of Nevada Administrative Code (NAC) Chapter 639. The proposed amendment authorizes the dispensing of a prescription drug to a practitioner instead of the ultimate user of the drug in certain circumstances. (LCB File No. R009-20)

President Park opened public comment.

Walgreens and CVS provided a written statement regarding proposed amendment changes to the Board for their review.

Lauren Paul, CVS Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Paul commented that she is concerned with the proposed amendment and requested the removal of the FDA's Risk Evaluation and Mitigation Strategy (REMS) requirement. The removal would allow the practitioner or the ultimate user to choose where to have the medication dispensed.

Elizabeth MacMenamin, Vice President of Government Affairs for the Retail Associate of Nevada, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. MacMenamin is in favor of the proposed amendment as mentioned by Walgreens.

Lorri Walmsley, Walgreens Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Walmsley commented that she is concerned with the limitations of drugs that pharmacies can dispense in this proposed amendment. In addition, she requested that the Board consider providing an option to destroy drugs by adhering to the pharmacy's procedures for the return of a prescription. With the changes suggested, the recipient can choose to donate or destroy a drug.

Board discussion ensued on the proposed amendment.

Ms. Walmsey suggested changing the timeframe to destroy a drug from 14 days to 30 days to provide more time to users.

Jade Jacobo excused herself at 9:38 AM.

Board Action:

Motion: Krystal Freitas moved to adopt the proposed Amendment for LCB File No. R009-20 with the proposed changes regarding the destruction of drugs from 14 days to 30 days and adding the option to return the drugs back to the pharmacy as long as it was not subsequently dispensed to another patient.

Second: Wayne Mitchell

Action: Passed unanimously (Jacobo not present for motion).

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

A. **Amendment Of Nevada Administrative Code (NAC) 639.220, 639.715, 639.718, and 639.720: Use of Mechanical Device to Dispense Prescription Drugs**. The proposed amendments will license the use of a mechanical device or an automated drug dispensing system to furnish a prescription drug to a patient and revise regulatory requirements for mechanical devices.

Mr. Kandt provided background on the proposed amendment.

President Park opened public comment.

Bob Parrado, Pharmacy Consultant for Onmed, commented that there's an automated medicine dispenser at the Las Vegas Convention Center. It will allow a patient to get drugs at the dispenser or get the prescription sent over to a pharmacy or practitioner.

Austin White, President and CEO of Onmed, commented that the medicine dispenser is patented and will provide a service of telemedicine with a clinician or a pharmacist.

Mr. Wuest commented that automated medicine dispensing machines need to be approved by the Board.

Board discussion ensued regarding the proposed amendment.

Board Action:

Motion: Wayne Mitchell moved to approve proposed Amendment of Nevada Administrative Code (NAC) 639.220, 639.715, 639.718, and 639.720: Use of Mechanical Device to Dispense Prescription Drugs and moved forward to Public Hearing.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo not present for motion).

B. **Amendment of Nevada Administrative Code (NAC) 639.** The proposed amendments will add a new section specifying that the Board will adopt by reference standards established pursuant to memorandum of understanding with the Food and Drug Administration for compounding pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).

Mr. Wuest provided background on proposed amendment and read the FDA Memorandum of Understanding (MOU) into the record.

President Park opened public comment.

There was no public comment.

Board discussion ensued regarding this proposed amendment.

Board Action:

Motion: Richard Tomasso moved to approved the proposed amendment and move forward to Public Hearing.

Second: Gener Tejero

Action: Passed unanimously (Jacobo not present for motion).

14. Applications for Out-of-State Compounding Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

D. Paragon Infusion Care, Inc. – Plano, TX

Heidi Robbin, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a letter of authorization for Ms. Robbin to speak on behalf of the company.

Mr. Dodge provided background regarding an ownership change and requested if they would like to remove the affidavit regarding sterile compounding.

Ms. Robbin confirmed that the affidavit should be removed.

Mr. Dodge questioned Ms. Robbin regarding the change in ownership, any operational changes, their disclosures, and the results of the Texas Board inspection of their location.

Ms. Robbin answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve the change of ownership for Paragon Infusion Care's Out-of-State Compounding Pharmacy license pending Texas Board of Pharmacy Inspection and letter of authorization.

Second: Wayne Mitchell

Action: Passed unanimously.

15. Applications for Out-of-State Pharmacy License – Appearance

B. Paragon Healthcare Specialty – Dallas, TX

Debbie Thompson, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a letter of authorization for Ms. Thompson to speak on behalf of the company.

Mr. Kandt provided background to the Board regarding their disclosures.

Board questioned Ms. Thompson regarding her business model regarding and the process of how their patients would administer drugs to themselves.

Ms. Thompson answered questions to the Board's satisfaction.

Board Action:

Motion: Wayne Mitchell moved to approve change of ownership for Paragon Healthcare Specialty Out-of-State Compounding Pharmacy License pending letter of authorization.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Huvepharma, Inc. – St. Louis, MO – Background Check Not Required – Manufacturer (NAC 639.593(7)(d)) – Disclosure

Amber Nielson (Regulatory Associate),Todd Noll (Facility Manager), Carla Casillas (QA Supervisor), and Jill Simpson (QA Project Manager) appeared and were sworn in by President Park prior to answering questions and offering testimony.

President Park requested a letter of authorization for Ms. Nielson, Mr. Noll, Ms. Casillas, and Ms. Simpson to speak on behalf of the company.

Ms. Lee provided background to the Board regarding their disclosures.

Ms. Nielson provided an explanation of the disclosures to the Board.

President Park questioned Ms. Nielson on what changes were made to ensure that administrative action will not happen again.

Ms. Nielson stated that they have a new site manager and licensing team to ensure that they are in compliance.

Board Action:

Motion: Richard Tomasso moved to approve Huvepharma, Inc. Out-of-State Wholesaler license pending letter of authorization.

Second: Gener Tejero

Action: Passed unanimously.

D. Teva Pharmaceuticals USA, Inc. – Chalfont, PA – Background Check Not Required – VAWD-Accredited (NAC 639.593(7)(c)) – Disclosure
E. Teva Pharmaceuticals USA, Inc. – North Wales, PA – Background Check Not Required – VAWD-Accredited (NAC 639.593(7)(c)) – Disclosure

Kelly O'Donoghue, Associate Director of Legal Affairs, and Timothy Hilden, DEA Compliance Auditor, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background to the Board regarding their disclosures.

Ms. O'Donoghue provided an explanation to the Board regarding their administrative action.

Mr. Wuest mentioned that Teva Pharmaceuticals USA, Inc helped all the states with drugs at the beginning of COVID.

President Park commented that she is comfortable going forward with the ownership change.
Board Action:

Motion: Krystal Freitas moved to approve change of ownership for Out-of-State Wholesaler License Teva Pharmaceuticals USA, Inc. in Chalfont, PA and North Wales, PA.

Second: Wayne Mitchell

Action: Passed unanimously.

Jade Jacobo joined the meeting at 11:22 AM.

17. Applications for Out-of-State Medical, Devices, Equipment and Gases License – Appearance (**FOR POSSIBLE ACTION**)

B. Owens & Minor Distribution, Inc. – Ontario, CA

Sarah Golas (Manager of Licensing), Sergio Gutierez (Managing Pharmacist), and Gerardo Castellanos (Distribution Supervisor) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background to the Board regarding their disclosures.

Board questioned Ms. Golas and Mr. Castellanos regarding the temperatures that they store drugs under and actions taken to ensure that their disclosures will not happen again.

Ms. Golas and Mr. Castellanos answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve Owens & Minor Distribution, Inc. Out-of-State Medical, Devices, Equipment and Gases license.

Second: Wayne Mitchell

Action: Passed unanimously.

11. Applications for Controlled Substance Registration - Appearance. (**FOR POSSIBLE ACTION)**

A. Hisbay Ali, MD

Hisbay Ali appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background to the Board regarding Mr. Ali's disclosure regarding a DUI. President Park requested an explanation of what happened with his disclosure and how he's changed since then.

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

Board discussion ensued regarding if Mr. Ali should get a PRN evaluation or equivalent.

Board Action:

Motion: Rolf Zakariassen moved to approve Hisbay Ali Controlled Substance registration.

Second: Jade Jacobo

Action: Passed unanimously.

16. Applications for Nevada Medical, Devices, Equipment and Gases License – Appearance (**FOR POSSIBLE ACTION**)

B. Wildcard Medical Inc. – Reno, NV

Matthew Sweeney, MDEG Administrator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background to the Board.

Board questioned Mr. Sweeney on his work experience, the business model, how he plans to get customers, and his past disclosure regarding a DUI.

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

Board Action:

Motion: Jade Jacobo moved to approve Wildcard Medical Inc. Medical, Devices, Equipment and Gases license pending favorable Board inspection.

Second: Krystal Freitas

Action: Passed unanimously.

13. Application for Nevada Pharmacy License – Appearance (**FOR POSSIBLE ACTION**)

E. US Pharmacy – Las Vegas, NV

Fernesser Tracey, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board.

Board questioned Ms. Tracey regarding the business model, her work experience, and her disclosure.

Ms. Tracey answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve US Pharmacy License.

Second: Rolf Zakariassen

Action: Passed unanimously.

26. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. COVID-19 Response
F. Licensing Software Update
G. Licensing Activities Report
H. PMP Integration

Mr. Wuest presented the financial report to the Board's satisfaction.

Mr. Kandt presented the legislative update to the Board's satisfaction.

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

This item was addressed in the Executive Secretary Report.

16. Applications for Nevada Medical, Devices, Equipment and Gases License – Appearance (**FOR POSSIBLE ACTION**)

A. Kinex Medical Company – Las Vegas, NV

Mike Buckholdt (CEO), Kelly Dove (Legal Counsel), and Lyn Beggs (Legal Counsel) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board.
Board staff found two pre-inspection issues at Kinex Medical Company which were 1) Kinex still operating after a cease-and-desist letter was sent out to the Hauck Street location 2) Kinex operating in an unlicensed off-site storage location.

Mr. Dodge called Ken Schuber, Nevada Board of Pharmacy Board Inspector, as a witness.

Mr. Schuber appeared was sworn in by President Park prior to answering questions and offering testimony.

Mr. Schuber testified regarding the pre-inspection issues that were found.

Ms. Beggs provided clarification that Kinex admits to servicing patients after the cease-and-desist letter to help their patients. However, the unlicensed off-site storage location that Kinex opened was specifically to retrieve returns and did not service patients since the office was closed.

Board discussion ensued on whether Kinex was properly noticed by the Board based on Ms. Beggs comment.

Mr. Wuest requested if Kinex would like to go forward with their application based on the information provided.

Ms. Beggs would like to table the application to the next Board Meeting.

President Park tabled Kinex Medical Company's application at its request.

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

B. Northwest Generics – Vancouver, WA – Background Check Not Required – Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d) – Disclosure

Jack Holt, part-owner, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Lee provided background to the Board regarding company's disclosure regarding recordkeeping issues.

Mr. Holt provided clarification regarding disclosure to the Board.

Board questioned Mr. Holt regarding the business model of the company.

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

Board Action:

Motion: Jade Jacobo moved to approve Northwest Generics Out-of-State Wholesaler license.

Second: Krystal Freitas

Action: Passed unanimously.

C. Organon, LLC – Kenilworth, NJ – Background Check completed in compliance with NRS 639.500 – No Disqualifying Events – Disclosure

Heather Koch, Licensing Senior Specialist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a letter of authorization for Ms. Koch to speak on behalf of the company.

Ms. Lee provided background to the Board regarding their disclosure relating to an internal audit issue.

Board Action:

Motion: Jade Jacobo moved to approve Organon, LLC Out-of-State Wholesaler license.

Second: Richard Tomasso

Action: Passed unanimously.

F. USWM, LLC – Louisville, KY - Background Check completed in compliance with NRS 639.500 –Disqualifying Events – Disclosure

Adam Reuther, Director of Regulatory Affairs, and Lee Warren, Chief Operating Officer, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Kandt provided background to the Board regarding Mr. Warren's disclosure relating to possession of an illegal substance.

Board requested when his disclosure occurred.

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

Board Action:

Motion: Krystal Freitas moved to approve USWM, LLC Out-of-State Wholesaler license.

Second: Wayne Mitchell

Action: Passed unanimously.

19. Application for Pharmacist Registration by Reciprocation – Appearance (**FOR POSSIBLE ACTION**)

B. Doan Tran

Doan Tran appeared and was sworn in by President Park prior to answering questions and offering testimony.

Ms. Long provided background on Mr. Tran's disclosure.

Board Action:

Motion: Jade Jacobo moved to approve Application for Pharmacist Registration by Reciprocation for Doan Tran.

Second: Rolf Zakariassen

Action: Passed unanimously.

20. Application for Out-of-State Outsourcing Facility – Appearance (**FOR POSSIBLE ACTION**)

RC Outsourcing, LLC – Lowellville, OH

Emily Carlson, Supervising Pharmacist, and Ray Carlson, Owner, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board.

Mr. Dodge questioned Ms. And Mr. Carlson regarding products and services provided, compounding policies and procedures, and past inspections with FDA.

Ms. and Mr. Carlson answered questions to the Board's satisfaction.

Board Action:

Motion: Krystal Freitas moved to approve RC Outsourcing, LLC Out-of-State Outsourcing Facility license.

Second: Jade Jacobo

Action: Passed unanimously.

21. Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Appearance **(FOR POSSIBLE ACTION)**

Applicants are requesting to practice pharmacy in a facility other than a licensed pharmacy. The services that the applicants would provide is chronic medication management relating to diabetes, cholesterol, hypertension, and hypothyroidism.

A. Krystal Riccio

President Park recused from participation in this matter as she works with Ms. Riccio.

Wayne Mitchell acting as presiding officer.

Krystal Riccio appeared and was sworn in by Wayne Mitchell prior to answering questions and offering testimony.

Ms. Riccio provided background on her practice. She commented that she needs to add two other locations to the application.

Board requested that she provide the other two locations via email after the meeting.

Board Action:

Motion: Jade Jacobo moved to approve Krystal Riccio's request to engage in the practice of pharmacy at a site other than a licensed pharmacy.

Second: Krystal Freitas

Action: Passed unanimously.

B. Mary Simon
C. Aron Suci

Mary Simon and Aron Suci appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Wuest provided background on her appearance regarding practicing outside of a licensed pharmacy.

Board requested the business model for the service that they are providing.

Ms. Simon answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve Mary Simon and Aron Suci's request to engage in the practice of pharmacy at a site other than a licensed pharmacy.

Second: Richard Tomasso

Action: Passed unanimously.

24. Discussion and possible action to amend, revise and/or approve proposed FY22 budget. **(FOR POSSIBLE ACTION)**

Mr. Wuest and Christian Schonlau, Chief Financial Officer of the Nevada Board of Pharmacy, presented the proposed FY22 budget.

Board discussion followed.

Board Action:

Motion: Jade Jacobo moved to approve proposed FY22 budget.

Second: Richard Tomasso

Action: Passed unanimously.

15. Applications for Out-of-State Pharmacy License – Appearance

A. OptionOne Infusion – Oklahoma City, OK

Ken Long, Director of Clinical Services for Amerita Specialty Infusion, and Chad Reese, Director of Pharmacy Operations at Optionone Infusion, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Mr. Dodge provided background to the Board regarding their disclosures.

Mr. Dodge questioned Mr. Long and Mr. Reese about their business model, the shipping process, and further clarification on what occurred with their disclosures.

Mr. Long and Mr. Reese answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve OptionOne Infusion Out-of-State Pharmacy license.

Second: Wayne Mitchell

Action: Passed unanimously.

17. Applications for Out-of-State Medical, Devices, Equipment and Gases License – Appearance (**FOR POSSIBLE ACTION**)

A. Medline Industries, Inc. – Northfield, IL

Tommy Roberts, Senior Director of Operations, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested if Mr. Roberts is eligible to speak on behalf of the company.

Mr. Roberts commented that he is allowed to speak as he is the Senior Director of Operations which includes regulatory affairs, pharmacy distribution, and pharmacy practice.

Mr. Wuest provided background to the Board regarding their disclosures.

Board requested further clarification on what occurred with their recent disclosures.

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

Board Action:

Motion: Krystal Freitas moved to approve Medline Industries, Inc. Out-of-State Medical, Devices, Equipment and Gases license.

Second: Jade Jacobo

Action: Passed unanimously.

23. Approval of Revised Medical Device, Equipment and Gases (MDEG) Application and MDEG Administrator Application. **(FOR POSSIBLE ACTION)**

Ms. Long presented the updated Medical Device, Equipment and Gases (MDEG) Application and MDEG Administrator Application to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve revised Medical Device, Equipment and Gases (MDEG) Application.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve revised Medical Device, Equipment and Gases (MDEG) Administrator Application.

Second: Krystal Freitas

Action: Passed unanimously.

19. Application for Pharmacist Registration by Reciprocation – Appearance (**FOR POSSIBLE ACTION**)

A. Ruth Mercy Magalit

No representative on behalf of Ms. Magalit was present.

Public comment June 3, 2021, 5:00pm

There was no public comment.

29. Date and Location of Next Scheduled Board Meeting:

July 15-16, 2021 – Las Vegas, NV

31. Adjournment

4

4A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH***_____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *ole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: A & M Pharmacy LLC

Physical Address: 6564 Winter Garden Rd. Orlando, Florida 32835

Mailing Address: 6564 Winter Garden Rd

City: Orlando State: Florida Zip Code: 33067

Telephone: (877) 211-0894 Fax: (855) 363-9914

Toll Free Number: (877) 211-0894 (Required per NAC 639.708)

E-mail: ampharm1@gmail.com Website: N/A

Managing Pharmacist: Christopher Y Perseo License Number: PS52369

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
All boxes must be checked		☐	☑ Mail Service Sterile Compounding **
For the application to be complete		☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Christopher Y Perseo — Print Name of Authorized Person

08.27.2020 — Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: A&M Corporate Holdings LLC

Mailing Address: 6564 Old Winter Garden Rd.

City: Orlando State: Florida Zip: 32835

Telephone: (877) 211-0894 Fax: (855) 363-9914

Contact Person: Christopher Perseo

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Christopher Perseo 100% 6564 Old Winter Garden Rd Orlando Florida 32835
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: None %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Christopher Y Perseo

Responsible Person of A & M Pharmacy LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Christopher Y Perseo
Print Name of Authorized Person

8.27.2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Florida)
) ss.
Palm Beach COUNTY)

I, Christopher Y Perseo, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President for A & M Pharmacy LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Christopher Perseo, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
27th day of August, 2020.

NOTARY PUBLIC

VIDYA BRIDGEMOHAN
NOTARY PUBLIC
STATE OF FLORIDA
Comm# GG317384
Expires 7/30/2023

Posted April 1, 2020

AC# 10010573

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/20/2021	PH 26511	121981

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy
Schedule II & III
2:1 Pharmacy Technician Ratio Approved

Expiration Date: **FEBRUARY 28, 2023**
A & M PHARMACY, LLC
A & M Pharmacy
6564 OLD WINTER GARDEN ROAD
ORLANDO, FL - 32835

Ron DeSantis
GOVERNOR

Scott A. Rivkees, MD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

AC# 10010573

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/20/2021	PH 26511	121981

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : FEBRUARY 28, 2023

A & M PHARMACY, LLC
A & M Pharmacy

REGISTRANT SIGNATURE

QUALIFICATION(S):
Community Pharmacy
Schedule II & III
2:1 Pharmacy Technician Ratio
Approved

State of Florida
Department of State

I certify from the records of this office that A & M PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on May 3, 2012, effective May 2, 2012.

The document number of this limited liability company is L12000059652.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on May 6, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Second day of June, 2021

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

Secretary of State

Tracking Number: 6546215158CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

AC#8618209

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/03/2018	PH 26511	103607

The **PHARMACY** named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2021**

A & M PHARMACY, LLC
A & M Pharmacy
6564 OLD WINTER GARDEN ROAD
ORLANDO, FL 32835

QUALIFICATION(S):
SCHEDULE II & III
COMMUNITY PHARMACY
2:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION
A3M Pharmacy	26511	3/4/2020
DOING BUSINESS AS		
STREET ADDRESS 6564 Old Winter Garden Road	TELEPHONE # 407-250-4022	EXT
CITY Orlando	COUNTY Orange	STATE/ZIP FL 32835

Additional Information

Business Operation Hours

Weekly Hours	M-T-W-TH-F

Registered Pharmacist / Intern / Tech

License # 45222	Licensee Name
License Type PH	Hamayoun Bhatti
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License # 5850	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	
License #	Licensee Name
License Type	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FA3257612	

License Relations

Pharmacy Affiliate

	License #
	License #

RX DPT MGR/COR/POR

Christopher Perez	License # 523169

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1091 (2) F.A.C.]	YES

PH 24571

INV359 - Community Requirements

Insp # File #

"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109 F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.] there were four dates on the active shelves	NO
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.] no techs currently employed	n/a
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.] no techs currently employed	N/A
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	n/a
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(i) F.S.] 2019/2020	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] 4/2020	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.] no theft or losses to date of the Law	Yes
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	n/a
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	n/a
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.787 F.A.C.]	n/a
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	n/a

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10301, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	n/a
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	n/a

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	n/a
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	n/a

INV359 - Community Requirements

Insp #

PH26511

File #

The originating pharmacy is identified with pharmacy name and address on the prescription container label.	n/a
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy. [64B16-28.450](4)	n/a
If a controlled substance, the word "central fill" appears on the face of the original prescription. [64B16-28.450](5)	n/a
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	n/a

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [456.0197 (3)(e), F.S.]	n/a
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [455.0197 (3)(e), F.S.]	n/a
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. (455.0197 (3)(e) F.S)	n/a

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date: 08/04/2020

Representative:

Date: 8/4/2020

A&M PHARMACY

6564 Old Winter Garden Rd.
Orlando, Florida 32835

Corporate Officers:
Christopher Y Perseo PharmD., RPh., President 100%

State of Florida
Department of State

I certify from the records of this office that A & M PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on May 3, 2012, effective May 2, 2012.

The document number of this limited liability company is L12000059652.

I further certify that said limited liability company has paid all fees due this office through December 31, 2020, that its most recent annual report was filed on March 20, 2020, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of July, 2020



Secretary of State

Tracking Number: 1190657885CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

August 6, 2020

A & M Pharmacy
Chris Perseo
6564 Old Winter Garden Rd
Orlando, Fl. 32835

RE: License Certification for A & M Pharmacy, LLC

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH26511
ORIGINAL CERTIFICATION:	11/20/2012
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Ronalda Crawford

Ronalda Crawford
Regulatory Specialist II

/rc

GREAT SEAL OF THE STATE OF FLORIDA · IN GOD WE TRUST ·

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX : (850) 245-4791

PHAB Accredited Health Department
Public Health Accreditation Board

4B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Adelaide Apothecary

Physical Address: 160 Moore Dr, STE 105 Lexington, KY 40503

Mailing Address: 160 Moore Dr Ste 105

City: Lexington State: KY Zip Code: 40503

Telephone: 502-334-8013 Fax: 859-909-8519

√ Toll Free Number: 833-920-2104 (Required per NAC 639.708)

E-mail: jill.smith@maynepharma.com Website: adelaideapothecary.com

Managing Pharmacist: Jill Smith License Number: KY 013547

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☑	☐ Other: Independent	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
All boxes must be checked		☐	☑ Mail Service Sterile Compounding **
For the application to be complete		☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Jill Smith

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jill Smith

Print Name of Authorized Person

5/10/2021

Date

Board Use Only	Date Processed:_____	Amount: 500 Check # 0300534710

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: North Carolina

Parent Company if any: Mayne Pharma, Inc

Mailing Address: 160 Moore Drive, Ste 105

City: Lexington State: KY Zip: 40503

Telephone: 859-909-8520 Fax: 859-909-8519

Contact Person: Jill Smith

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: %:

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday Closed am Closed pm

Sunday Closed am Closed pm 24 Hours NO

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number:

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Jill L Smith, RPh

Responsible Person of Adelaide Apothecary

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jill L Smith, RPh
Print Name of Authorized Person

5/10/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Kentucky)
) ss.
Scott COUNTY)

I, Jill Smith, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager for Adelaide Apothecary (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Jill Smith, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
10 day of May, 2021.

NOTARY PUBLIC

Griffin Allen Bennett
Notary Public, ID KYNP11900
State at Large, Kentucky
My Commission Expires on July 29, 2024

Posted April 1, 2020

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(Long Form)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

ADELAIDE APOTHECARY LLC

is a limited liability company duly formed, and existing under the laws of the State of North Carolina, having been organized on 11th day of January, 2021, under the name Perpetual, under the name Adelaide 1836 LLC and that the following documents have been filed since that date:

Date	Event	Filed Document
1/11/2021	Creation Filing	Articles of Organization Limited Liability
2/19/2021	Name Change	Corporation Name Change (Domestic)

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 10th day of May, 2021.

Elaine F. Marshall

Secretary of State

Scan to verify online.

I, FURTHER certify that no record is found of other Company documents having been filed since the 19th day of February, 2021

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company is not dissolved under the terms of its articles of organization, (ii) the said limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 10th day of May, 2021.

Elaine F. Marshall

Secretary of State

Scan to verify online.

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Resident Pharmacy

EFFECTIVE DATE: 02/10/2021

NUMBER: P08167

EXPIRATION DATE: 06/30/2022

PIC: JILL LYNNE SMITH

Issued to:
ADELAIDE APOTHECARY

160 MOORE DR
SUITE 105
LEXINGTON, KY 40503

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address. and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

jill.smith@maynepharma.com

Adelaide Apothecary
LLC Information

Daniel Moore, President
[redacted] Benson Dr, Ste [redacted]
Raleigh, NC 27609

Kathy Twiddy, Secretary
[redacted] Benson Dr, Ste [redacted]
Raleigh, NC 27609

KENTUCKY BOARD OF PHARMACY

Andy Beshear
Governor

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
http://pharmacy.ky.gov

Board Members
Peter P. Cohron, R.Ph.
Jody Forgy, Consumer
John Fuller, R.Ph.
Christopher Harlow, Pharm D.
Jill Rhodes, Pharm.D.
Jonathan Van Lahr, R.Ph.

Executive Director
Larry A. Hadley, R.Ph.

STATE OF KENTUCKY

COUNTY OF FRANKLIN

PERMIT HOLDER: **ADELAIDE APOTHECARY**
160 MOORE DR
SUITE 105
LEXINGTON, KY 40503

PERMIT NUMBER: **P08167**

I, Larry A. Hadley, Executive Director of the Kentucky Board of Pharmacy, do hereby certify that I am an official custodian of the records of said Board and that **ADELAIDE APOTHECARY** does not have any actions on file and does not have any current actions pending with the Kentucky Board of Pharmacy.

ADELAIDE APOTHECARY currently holds an active Kentucky pharmacy permit; permit number **P08167**, effective 02/10/2021 which will expire on June 30, 2021.

Witness my official hand and seal of the Board on March 9, 2021.

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

4C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Benecard Central Fill of FL, LLC

Physical Address: 28000 Spanish Wells Blvd, Bonita Springs, FL 34135

Mailing Address: 28000 Spanish Wells Blvd

City: Bonita Springs State: FL Zip Code: 34135

Telephone: 239-301-5760 Fax: 239-301-5781

Toll Free Number: 888-907-0090 (Required per NAC 639.708)

E-mail: bcf_licensing@benecard.com Website: www.benecardcentralfill.com

Managing Pharmacist: Bhairavi Youngblood License Number: PS38498

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☒ Parenteral **
☒	☐ Internet	☒	☐ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: Mail Order	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
All boxes must be checked		☐	☒ Mail Service Sterile Compounding **
For the application to be complete		☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Michael A Perry

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael A. Perry, President — 11/4/2020

Print Name of Authorized Person — Date

Board Use Only	Date Processed:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: N/A

Mailing Address: 28000 Spanish Wells Blvd

City: Bonita Springs State: FL Zip: 34135

Telephone: 239-301-5760 Fax: 239-301-5781

Contact Person: Maria Minelli, Licensing Manager, 609-219-0400 ext 5059, bcf_licensing@benecard.com

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) None - please see attached ownership explanation.
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. None - please see attached ownership explanation.

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A

List any physician shareholders and percentage of ownership.

Name: None %: _____

Name: None %: _____

Hours of operation for the pharmacy:

Monday thru Friday 9 am 5:30 pm Saturday Closed am _____ pm

Sunday Closed am _____ pm 24 Hours Pharmacists available via phone 24/7 at toll free number

[illegible] if the pharmacy has a Nevada business license please provide the number: E8893132020-0

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Michael A. Perry

Responsible Person of Benecard Central Fill of FL, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael A. Perry, President
Print Name of Authorized Person

11/4/2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Pennsylvania)
) ss.
Cumberland COUNTY)

I, Michael A. Perry, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President for Benecard Central Fill of FL, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Michael A. Perry, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
4th day of November, 2020.

NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
Danelle D. Johnson, Notary Public
Cumberland County
My commission expires March 20, 2023
Commission number 1256540
Member, Pennsylvania Association of Notaries

Benecard Central Fill of FL, LLC
Nevada Out-of-State Pharmacy License Application
Application Section: Ownership is a Non Publicly Traded Corporation

As an LLC, Benecard Central Fill of FL, LLC ("BCFFL") does not issue shares. The owners are the three LLC Members listed below, each with equal 33 1/3% ownership interest in the company.

- Kenneth D. Ullman
  [redacted] S. Tamiami Trail
  Bonita Springs, FL 34134

- Richard A. Ullman
  [redacted] Route 46 West
  Clifton, NJ 07013

- Jennifer A. Royall
  [redacted] S. Tamiami Trail
  Bonita Springs, FL 34134

Benecard Central Fill of FL, LLC
Nevada Out-of-State Pharmacy License Application
Application Attachment: List of Officers and Directors

Name	Position	Address
Kenneth Douglas Ullman	LLC Member, Chairman	[redacted]S. Tamiami Trail Bonita Springs, FL 34134
Richard Arthur Ullman	LLC Member, Vice Chairman	[redacted]Route 46 West Clifton, NJ 07013
Jennifer Anne Royall	LLC Member, Director	[redacted]S. Tamiami Trail Bonita Springs, FL 34134
Donald Eugene Schell	Director	[redacted]Ritter Rd Mechanicsburg, PA 17055
Steven Nicholas Nicoletos	Director, Assistant Secretary, Assistant Treasurer	[redacted]Route 46 West Clifton, NJ 07013
Michael Anthony Perry	President	[redacted]Ritter Rd Mechanicsburg, PA 17055
Richard Bernard Terranova	Vice President, Secretary, Treasurer, CFO	[redacted]Route 46 West Clifton, NJ 07013

State of Florida
Department of State

I certify from the records of this office that BENECARD CENTRAL FILL OF FL, LLC. is a limited liability company organized under the laws of the State of Florida, filed on April 3, 2012.

The document number of this limited liability company is L12000045841.

I further certify that said limited liability company has paid all fees due this office through December 31, 2020, that its most recent annual report was filed on March 20, 2020, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-eighth day of July, 2020



Secretary of State

Tracking Number: 8139158728CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the Healthiest State in the Nation

August 26, 2020

Benecard
Maria Minelli
3131 Princeton Pike
Bld 2B, Ste 103
Lawrenceville, NJ 08648

RE: License Certification for Benecard Central Fill of FL, LLC,

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH30527
ORIGINAL CERTIFICATION:	12/20/2016
EXPIRATION DATE:	02/28/2021
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gerlisia K. Still
Regulatory Specialist II

/gs

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX : (850) 245-4791

PHAB Accredited Health Department
Public Health Accreditation Board

AC#8721946

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/03/2019	PH 30527	106774

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: FEBRUARY 28, 2021

BENECARD CENTRAL FILL OF FL, L.L.C.
28000 SPANISH WELLS BLVD
BONITA SPRINGS, FL 34135

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
AC# 8721946

DATE	LICENSE NO.	CONTROL NO.
01/03/2019	PH 30527	106774

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: FEBRUARY 28, 2021

QUALIFICATION(S):
Community Pharmacy
Schedule II & III

EXPIRATION DATE: FEBRUARY 28, 2021

Your license number is PH 30527. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received you renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A Lic to renew online.

Medical Quality Assurance has a new and improved Online Services Portal. In the new system, you have the ability to renew your licens update your mailing and practice location addresses, request a name change, request a duplicate license and update your profile information all from the convenience of your online account.

1. Go to www.FLHealthSource.gov.
2. Click on "Provider Services" and select "Manage Your License."
3. Select your profession and license type and click "Submit."
4. The question "Have you Renewed or Applied Online Since 2015?" will display.
   a. Click on "No" if you have not registered for an account in the new system and follow the instructions provided for new use registration.
   b. Click on "Yes" if you are a returning user. Enter the user ID and password you selected during the registration process, th select "Sign In" to access your MQA Online Services Portal account.

IMPORTANT ANNOUNCEMENTS

Are You Renewal Ready?

The Department of Health will now review your continuing education records at the time of license renewal.

To learn more, please visit www.FLHealthSource.gov/AYRR

Grounds for Discipline

You should be familiar with the Grounds Discipline found in Section 456.072(1), Florida Statutes, and in the practice act fi the profession in which you are licensec Florida Statutes can be accessed at www.leg.state.fl.us/Statutes

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application
(Only required if providing internet services)

GENERAL INFORMATION

Name of Nevada license pharmacy: Benecard Central Fill of FL, LLC

Nevada license number: Application in progress

Websites in use or intended to be used: www.benecardcentralfill.com

Affiliated websites (websites that link to or otherwise direct users to your website):
http://www.benecardpbf.com/

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☐ No ☑

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☑ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:

A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☑ No ☐

B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☑ No ☐

C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☑ No ☐

D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☑ No ☐

E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☑ No ☐

F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☑ No ☐

G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☑ No ☐

H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☑ No ☐

I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☑ No ☐

J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☑ No ☐

3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☑ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☑ No ☐

5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☑ No ☐

6. Does the pharmacy comply with applicable federal and state laws regarding the following:

   A) To the dispensing of prescription drugs? Yes ☑ No ☐

   B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☑ No ☐

   C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs ? Yes ☑ No ☐

7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☑ No ☐

8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia, 25th* edition, 2002, which is hereby adopted by reference? Yes ☑ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.

_____, President _____ 11/4/2020

Signature of Owner Date

Benecard Central Fill of FL, LLC
List of Pharmacy and Controlled Substance Licenses

State of Licensure	Date of Initial Licensure	License Number
Alabama*	02/27/2019	114897
Arkansas*	03/07/2018	OS02864
California*	05/18/2020	NRP 2338
Connecticut*	10/23/2020	PCN.0003870
Florida*	12/20/2016	PH 30527
Georgia*	11/01/2017	PHNR001296
Hawaii	04/16/2019	PMP-1599
Hawaii Controlled Substance	05/31/2019	E14316
Idaho*	01/24/2020	57014MS
Illinois	09/30/2020	054.021719
Illinois Controlled Substance	09/30/2020	320.013380
Iowa	09/18/2019	5132
Iowa Controlled Substance	09/18/2019	1108740
Louisiana*	11/13/2018	PHY.007803-NR
Maine*	06/04/2018	MO40002333
Maryland	08/30/2017	P07631
Maryland Controlled Substance	09/20/2017	495549
Minnesota*	10/08/2020	266204
Mississippi	04/19/2018	17068/7.1
Mississippi Controlled Substance	04/19/2018	CS-17068 / 7.1
New Jersey*	05/31/2018	28RO00174300
New York*	03/27/2018	036503
North Carolina*	09/09/2019	14177
Ohio*	10/02/2020	0242000236
Oklahoma	08/22/2018	99-8265
Oklahoma Controlled Substance	08/31/2018	58993
Pennsylvania*	05/23/2018	NP001135
South Carolina	09/27/2018	18170
South Carolina Controlled Substance	03/04/2019	13-18170
Tennessee*	07/03/2017	00006027
Texas*	02/20/2018	31872
Virginia*	03/15/2018	0214002054

*Does not offer a separate Controlled Substance license.

Benecard Central Fill of FL, LLC

Policies and Procedures

2.

A) Prescriptions are received by phone directly from the doctor, via fax, electronic prescriptions, or by mail directly from patient. If there is concern regarding the authenticity of a prescription, the pharmacist contacts the doctor's office directly to confirm that they sent it to us, and that it is a legitimate prescription.

B) The pharmacy's adjudication system will not allow any early fills or duplications, or duplicate therapy. Pharmacist must address each rejection/DUR/dr consult or patient consult, individually, to determine whether a prescription is ok to fill at any given time.

C) The pharmacy system will reject any duplicates during adjudication for any prescription that was filled elsewhere. Additionally, for controlled substance prescriptions, the pharmacist must review PDMP prior to approving any prescription for dispensing. If there are clinical questions that arise from a patient's therapy, pharmacist must address them first, before the prescription can move forward to dispensing, packing and shipping.

D) Benecard Central Fill of FL, LLC will dispense prescriptions to patients who are members of any client group that contracts with us. Thus, the prescriptions we fill are only for our members, whom we identify by three different points of identification for each fill. Prescribers are identified by NPI and DEA numbers, and for controlled substances, we look for, and address, red flags prior to approving a prescription for dispensing.

E) Benecard Central Fill of Florida, LLC has pharmacists licensed in the states that we ship to, so that we are familiar with the laws of each of those states. Also, we have electronic access to all states and their respective regulations, should any questions arise. Benecard Central fill of Florida, LLC, also subscribes to newsletters for each state, so that we may remain updated on new and upcoming regulations, and make appropriate changes to the business, to comply with those laws.

F) A pharmacist is available 24/7, year-round, to address any patient concerns or complaints. This means a pharmacist is available to patients or their caregivers day or night, every day of the year.

G) Benecard Central Fill of Florida takes any patient concerns or complaints very seriously. If a patient complaint cannot be addressed by the pharmacist immediately, then we investigate as soon as feasible to determine the root cause, and address the complaint to the patient's full satisfaction.

H) For any error discovered, Benecard Central Fill of FL, LLC, investigates to determine the root cause of the error. Based on the findings, we re-write our policies and procedures in order to avoid the same error from re-occurring. All staff are retrained in the area of weakness, if discovered, so that they know how to prevent such an error again.

I) Any prescription which is delayed for any reason is communicated to the patient and their prescriber including the reason for the delay, anticipated date for shipment and what actions the pharmacy is

taking to prevent interruption of therapy for the patient. If necessary, the patient is always permitted use of a local pharmacy at any point in time, to prevent delay or interruption of therapy.

J) Benecard Central Fill of Florida, LLC tracks all lot numbers and expiration dates on any prescription. If the lot number is recalled, all affected patients are contacted with information on how to handle the drug recall. Every prescription that is shipped is accompanied by a statement, which provides patients information on how to dispose of expired, damaged or unusable drugs or devices.

3. With each prescription shipped, the pharmacy sends to patients a patient information sheet where they can enter current medications, health conditions and allergies.

4. The pharmacy system is designed to alert the pharmacist in case of situations that require Drug Utilization Review, who in turn will contact the prescriber, and the patient to resolve the alert, prior to dispensing.

5. Benecard Central Fill of FL, LLC utilizes Benecard's own pharmacy system, and security is rigidly maintained with the support of IS and IT staff. Patient sensitive information must be segregated in a separate locked bin for PHI, and shredded.

6.

A) Dispensing is performed one prescription at a time, using bar code technology and counting machines, to ensure that the correct medication is being dispensed to the correct patient. Hazardous Drugs are hand-counted using a counting tray in a designated HD section.

B) Prescription records are maintained for a period of 7 years. Inventory records are to be maintained for 4 years per Florida State laws. All records are also maintained electronically, indefinitely.

C) Benecard Central Fill of FL, LLC only dispenses medications upon receipt of a prescription.

7. Prescriptions are shipped using USPS, FedEx, or UPS, based on the patient's preference. For refrigerated and specialty medications, each patient receives an additional consultation to determine how they are doing on the medication and when, how, and where they want their medicine shipped. All packages can be tracked.

8. All prescriptions are dispensed in amber bottles to prevent light exposure, and shipped in poly bags or boxes with bubble wrap, that also prevent light exposure. Refrigerated medications are stored in temperature-controlled refrigerators, and the temperatures are recorded 24 hours a day. Refrigerated and Refrigerated Specialty medications are always shipped overnight, after confirming with the patient where and when they would like their medicine delivered. Benecard's software alerts us to temperatures in the shipping zip codes for the following few days, thus allowing us to include sufficient ice packs to maintain proper temperature. Benecard Central Fill of FL, LLC uses tested insulated shipping coolers for temperature sensitive shipping, which can maintain refrigerator temperatures (2-8 degrees Celsius) for up to 36 hours.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

May 13, 2021

Rebecca Hamdan
78 Hillcrest Ave.
2nd Floor
Woodland Park, NJ 07424

RE: License Certification for Benecard Central Fill Of Fl, L.l.c

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

PROFESSION:	Pharmacy
LICENSE NUMBER:	PH30527
ORIGINAL CERTIFICATION:	12/20/2016
EXPIRATION DATE:	02/28/2023
CURRENT STATUS OF LICENSE:	CLEAR,
AGENCY ACTION:	No
OTHER CERTIFICATIONS:	Community Pharmacy, Schedule Ii & Iii

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Willie Gaines
Regulatory Specialist II

/wg

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX : (850) 245-4791

PHAB Accredited Health Department
Public Health Accreditation Board

State of Florida
Department of State

I certify from the records of this office that BENECARD CENTRAL FILL OF FL, LLC. is a limited liability company organized under the laws of the State of Florida, filed on April 3, 2012.

The document number of this limited liability company is L12000045841.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on April 13, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventeenth day of May, 2021

Secretary of State

Tracking Number: 4534317663CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

4D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH***_____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Legal Name: Beth Israel Lahey Health Pharmacy Inc DBA Name: BILH Pharmacy Direct

Physical Address: 80 Wilson Way, Suite A Westwood MA 02090

Mailing Address: 80 Wilson Way, Suite A

City: Westwood State: MA Zip Code: 02090

Telephone: 781-352-6500 Fax: 781-352-6680

Toll Free Number: 1-866-916-0370 (Required per NAC 639.708)

E-mail: BILHPharmacyInc@bilh.org Website: www.BIDMC.org

Managing Pharmacist: Emmett Hayes License Number: PH23265

TYPE OF PHARMACY AND	SERVICES PROVIDED
Yes/No	Yes/No
☒ ☐ Retail	☐ ☒ Off-site Cognitive Services
☐ ☒ Hospital (# beds____)	☐ ☒ Parenteral **
☐ ☒ Internet	☐ ☒ Parenteral (outpatient)
☐ ☒ Nuclear	☐ ☒ Outpatient/Discharge
☐ ☒ Ambulatory Surgery Center	☒ ☐ Mail Service
☒ ☐ Community	☐ ☒ Long Term Care
☐ ☒ Other: _____	☐ ☒ Sterile Compounding **
	☐ ☒ Non Sterile Compounding
All boxes must be checked	☐ ☒ Mail Service Sterile Compounding **
For the application to be complete	☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Print Name of Authorized Person: Quan Pho

Date: 01-18-2021

Board Use Only Date Processed:_____ Amount: 500 Check # 001031

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: MA Corporate Ownership Structure

Parent Company if any: is attached

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. Zero

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 6 pm

Saturday CLOSED am pm

Sunday CLOSED am pm

24 Hours No

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: n/a

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Quan Pho

Responsible Person of Beth Israel Lahey Health Pharmacy Inc hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Quan Pho
Print Name of Authorized Person

01-18-2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF MA)
) ss.
Norfolk COUNTY)

I, Quan Pho, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer for Beth Israel Lahey Health Pharmacy Inc (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Quan Pho, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
18 day of January, 2021.

David L Young
NOTARY PUBLIC

David L. Young
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires August 5, 2027

Beth Israel Lahey Health

Corporate Ownership Structure

Parent 2	
Legal Name	Beth Israel Lahey Health, Inc.
Tax ID#	83-2671600
Address	20 University Road, Suite 700
City	Cambridge
State	MA
Zip	02138
Phone	617-667-7000
Fax	617-667-1736
Email Address	Jamie.Katz@BILH.org

Parent 1	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
Tax ID#	82-2526816
Address	80 Wilson Way, Suite B
City	Westwood
State	MA
Zip	02090
Phone	781-352-6700
Fax	781-352-6690
Email Address	BILHPharmacyInc@bilh.org

Beth Israel Lahey Health Pharmacy, Inc. is the corporation that owns the following DBAs:

1.) BILH Pharmacy Direct

2.) BILH Specialty Pharmacy

Pharmacy 1 (DBA)	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
DBA Name	BILH Pharmacy Direct
Tax ID#	82-2526816
Address	80 Wilson Way, Suite A
City	Westwood
State	MA
Zip	02090
Phone	781-352-6500
Fax	781-352-6680

Pharmacy 2 (DBA)	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
DBA Name	BILH Specialty Pharmacy
Tax ID#	82-2526816
Address	80 Wilson Way, Suite B
City	Westwood
State	MA
Zip	02090
Phone	781-352-6600
Fax	781-352-6610

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500, 5th Floor
Boston, MA 02114
Tel: 800-414-0168
Fax: 617-973-0983
TTY: 617-973-0988
www.mass.gov/dph/boards

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

BILH Pharmacy Direct
Emmett A Hayes
80 Wilson Way
Suite A
Westwood MA 02090

April 13, 2021

Certified Statement of Registration

To Whom It May Concern:

The individual named below is licensed in the Commonwealth of Massachusetts as a **Retail Drug Store Permit**.

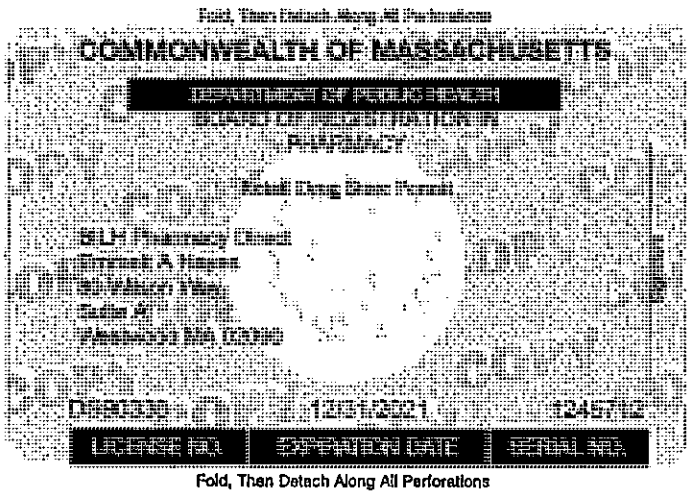
Name of Licensee:	**BILH Pharmacy Direct**
License Number:	**DS90336**
Issue Date:	**09/01/2020**
License Status:	**Current**
Expiration Date:	**12/31/2021**
Disciplinary Actions:	**None**

David Sencabaugh
Director
Board of Registration in PHARMACY SEAL

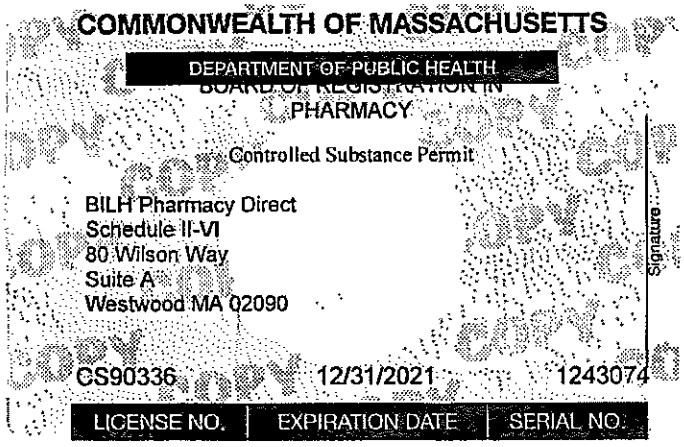
Registration verification can be obtained at https://checkalicense.hhs.state.ma.us/.
The information provided in this 'Certified Statement' is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the 'Certified Statement.' Disciplinary status is defined as voluntary surrender, revocation, suspension, or probation of a license.

For more information about the board, please visit our web site at http://www.mass.gov/dph/boards.

BILH Pharmacy Direct
Emmett A Hayes
80 Wilson Way
Suite A
Westwood MA 02090



Fold, Then Detach Along All Perforations



COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH

BOARD OF REGISTRATION IN PHARMACY

Controlled Substance Permit

BILH Pharmacy Direct
Schedule II-VI
80 Wilson Way
Suite A
Westwood MA 02090

Signature

CS90336 | 12/31/2021 | 1243074

LICENSE NO. | EXPIRATION DATE | SERIAL NO.

COPY

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: March 19, 2021

To Whom It May Concern :

I hereby certify that according to the records of this office,

BETH ISRAEL LAHEY HEALTH PHARMACY, INC.

is a domestic corporation organized on **August 17, 2017**

I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 180 section 26 A, for revocation of the charter of said corporation; that the State Secretary has not received notice of dissolution of the corporation pursuant to Massachusetts General Laws, Chapter 180, Section 11, 11A, or 11B; that said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

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

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 21030554210

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: NMa

Corporate Officers							
Name	Title 1	Title 2	Personal Street	Personal City	Personal State	Personal Zip	Personal Phone
Nate Horwitz-Willis	Director	Founding Principal, Leliwop	[redacted] Washington St [redacted]	Boston	MA	02124	[redacted]
Michael Rowan	Director	Executive Vice President, Hospital and Ambulatory Services, BILH	[redacted] Dedham St	Newton	MA	02461	
Quan Pho	Director	Chief Pharmacy Officer, BILH	[redacted] E. Fair Place	Aurora	CO	80016	
Nicole Devita	Director	Chief Operating Officer, BILH	[redacted] Old Haswell Park Rd	Middleton	MA	01949	
Richard Fernandez	Director	President, BID-Milton	[redacted] Woodledge Rd	Needham	MA	02492	
Efstathios (Stathis) Antoniades	Director	Chief Operating Officer, LHMC	[redacted] Newton St	Brookline	MA	02445	
Connie Woodworth	Director	Vice President of Finance, Beverly & Addison Gilbert Hospitals	[redacted] Middlebury Lane	Beverly	MA	01915	
Michael Cullen	Director	Chief Financial Officer, BIDMC	[redacted] Hayden Hollow	Plymouth	MA	02360	

Corporate Officer Info
PAGE 1 OF 2

Corporate Officers								
Name	Title 1	Title 2	Business Street	Business City	Business State	Business Zip	Business Phone	Business Fax
Nate Horwitz-Willis	Director	Founding Principal, Leliwop	719 Washington St #202	Boston	MA	02124	501-551-1778	781-352-6690
Michael Rowan	Director	Executive Vice President, Hospital and Ambulatory Services, BILH	20 University Road, Suite 700	Cambridge	MA	02138	617-278-8873	617-661-5365
Quan Pho	Director	Chief Pharmacy Officer, BILH	80 Wilson Way, Suite B	Westwood	MA	02090	781-352-6700	781-352-6610
Nicole Devita	Director	Chief Operating Officer, BILH	701 Edgewater Park Drive	Wakefield	MA	01880	978-236-1655	617-754-1040
Richard Fernandez	Director	President, BID-Milton	199 Reedsdale Rd	Milton	MA	02186	617-313-1353	617-313-1565
Efstathios (Stathis) Antoniades	Director	Chief Operating Officer, LHMC	41 Mall Rd	Burlington	MA	01805	781-744-8594	781-744-2785
Connie Woodworth	Director	Vice President of Finance, Beverly & Addison Gilbert Hospitals	85 Herrick St	Beverly	MA	01915	978-816-2587	978-921-7071
Michael Cullen	Director	Chief Financial Officer, BIDMC	80 Wilson Way, Suite B	Westwood	MA	02090	781-352-6700	781-352-6610

4E

#2 110

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and **not transferable money order or cashier's check only)**

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8* ☐ *Partnership - Pages 1,2,6,8*

☒ *Non Publicly Traded Corporation – Pages 1,2,4,8* ☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Legal Name: Beth Israel Lahey Health Pharmacy, Inc DBA Name: BILH Specialty Pharmacy

Physical Address: 80 Wilson Way, Suite B Westwood MA 02090

Mailing Address: 80 Wilson Way, Suite B

City: Westwood State: MA Zip Code: 02090

Telephone: 781-352-6600 Fax: 781-352-6610

Toll Free Number: 1-833-884-3600 (Required per NAC 639.708)

E-mail: BILHPharmacyInc@bilh.org Website: www.BIDMC.org

Managing Pharmacist: Luca Cattaneo License Number: PH21446

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☒	☐ Community	☐	☒ Long Term Care
☒	☐ Other: Specialty	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
All boxes must be checked		☐	☒ Mail Service Sterile Compounding **
For the application to be complete		☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Quan Pho
Print Name of Authorized Person

01-18-2021
Date

Board Use Only Date Processed:_____ Amount: 500 Check #001032

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: MA Corporate Ownership Structure

Parent Company if any: is Attached

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. Zero

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 6 pm

Saturday CLOSED am pm

Sunday CLOSED am pm

24 Hours NO

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Quan Pho

Responsible Person of Beth Israel Lahey Health Pharmacy Inc hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Quan Pho
Print Name of Authorized Person

01-18-2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF MA)
) ss.
Norfolk COUNTY)

I, Quan Pho, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer for Beth Israel Lahey Health Pharmacy Inc (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Quan Pho, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
18 day of January, 2021.

NOTARY PUBLIC

David L. Young
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires
August 5, 2027

Beth Israel Lahey Health

Corporate Ownership Structure

Parent 2	
Legal Name	Beth Israel Lahey Health, Inc.
Tax ID#	83-2671600
Address	20 University Road, Suite 700
City	Cambridge
State	MA
Zip	02138
Phone	617-667-7000
Fax	617-667-1736
Email Address	Jamie.Katz@BILH.org

Parent 1	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
Tax ID#	82-2526816
Address	80 Wilson Way, Suite B
City	Westwood
State	MA
Zip	02090
Phone	781-352-6700
Fax	781-352-6690
Email Address	BILHPharmacyInc@bilh.org

Beth Israel Lahey Health Pharmacy, Inc. is the corporotion that owns the following DBAs:

1.) BILH Pharmacy Direct

2.) BILH Speciolty Phormocy

Pharmacy 1 (DBA)	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
DBA Name	BILH Pharmacy Direct
Tax ID#	82-2526816
Address	80 Wilson Way, Suite A
City	Westwood
State	MA
Zip	02090
Phone	781-352-6500
Fax	781-352-6680

Pharmacy 2 (DBA)	
Legal Name	Beth Israel Lahey Health Pharmacy, Inc.
DBA Name	BILH Specialty Pharmacy
Tax ID#	82-2526816
Address	80 Wilson Way, Suite B
City	Westwood
State	MA
Zip	02090
Phone	781-352-6600
Fax	781-352-6610

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
239 Causeway Street, Suite 500, 5th Floor
Boston, MA 02114
Tel: 800-414-0168
Fax: 617-973-0983
TTY: 617-973-0988
www.mass.gov/dph/boards

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

BILH Specialty Pharmacy
Luca Cattaneo
80 Wilson Way
Suite B
Westwood MA 02090

April 13, 2021

Certified Statement of Registration

To Whom It May Concern:

The individual named below is licensed in the Commonwealth of Massachusetts as a **Retail Drug Store Permit**.

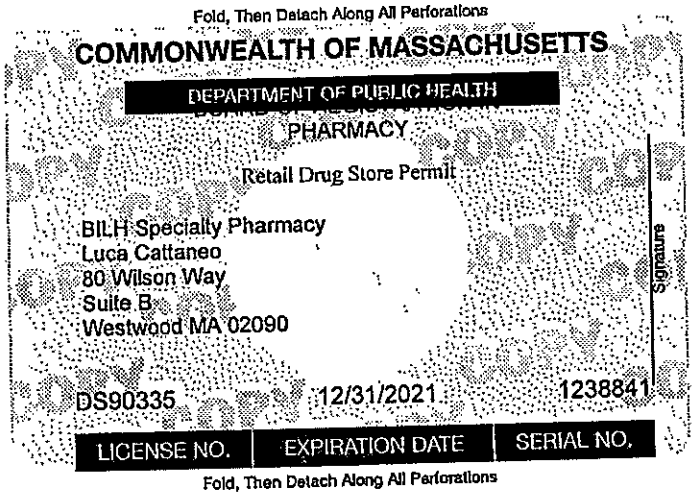
Name of Licensee:	**BILH Specialty Pharmacy**
License Number:	**DS90335**
Issue Date:	**08/19/2020**
License Status:	**Current**
Expiration Date:	**12/31/2021**
Disciplinary Actions:	**None**

David Sencabaugh
Director
Board of Registration in PHARMACY SEAL

Registration verification can be obtained at https://checkalicense.hhs.state.ma.us/.
The information provided in this 'Certified Statement' is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Individuals are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the 'Certified Statement.' Disciplinary status is defined as voluntary surrender, revocation, suspension, or probation of a license.

For more information about the board, please visit our web site at http://www.mass.gov/dph/boards.

BILH Specialty Pharmacy
Luca Cattaneo
80 Wilson Way
Suite B
Westwood MA 02090


Fold, Then Detach Along All Perforations

COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH

PHARMACY

Retail Drug Store Permit

BILH Specialty Pharmacy
Luca Cattaneo
80 Wilson Way
Suite B
Westwood MA 02090

Signature

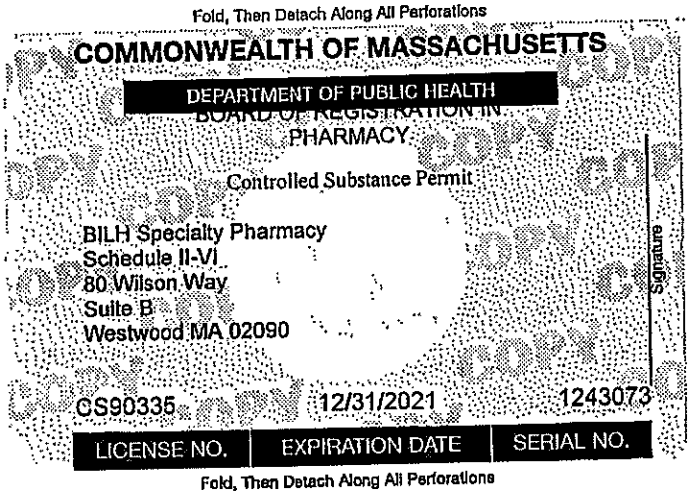
DS90335 12/31/2021 1238841

LICENSE NO. | EXPIRATION DATE | SERIAL NO.

Fold, Then Detach Along All Perforations

For more information about the board, please visit our web site at http://www.mass.gov/dph/boards.

BILH Specialty Pharmacy
Schedule II-VI
80 Wilson Way
Suite B
Westwood MA 02090



The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: March 19, 2021

To Whom It May Concern :

I hereby certify that according to the records of this office,

BETH ISRAEL LAHEY HEALTH PHARMACY, INC.

is a domestic corporation organized on **August 17, 2017**

I further certify that there are no proceedings presently pending under the Massachusetts General Laws Chapter 180 section 26 A, for revocation of the charter of said corporation; that the State Secretary has not received notice of dissolution of the corporation pursuant to Massachusetts General Laws, Chapter 180, Section 11, 11A, or 11B; that said corporation has filed all annual reports, and paid all fees with respect to such reports, and so far as appears of record said corporation has legal existence and is in good standing with this office.

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

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 21030554210

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: NMa

Corporate Officers							
Name	Title 1	Title 2	Personal Street	Personal City	Personal State	Personal Zip	Personal Phone
Nate Horwitz-Willis	Director	Founding Principal, Leliwop	[redacted] Washington St #202	Boston	MA	02124	[redacted]
Michael Rowan	Director	Executive Vice President, Hospital and Ambulatory Services, BILH	[redacted] Dedham St	Newton	MA	02461	
Quan Pho	Director	Chief Pharmacy Officer, BILH	[redacted] E. Fair Place	Aurora	CO	80016	
Nicole Devita	Director	Chief Operating Officer, BILH	[redacted] Old Haswell Park Rd	Middleton	MA	01949	
Richard Fernandez	Director	President, BID-Milton	[redacted] Woodledge Rd	Needham	MA	02492	
Efstathios (Stathis) Antoniades	Director	Chief Operating Officer, LHMC	[redacted] Newton St	Brookline	MA	02445	
Connie Woodworth	Director	Vice President of Finance, Beverly & Addison Gilbert Hospitals	[redacted] Middlebury Lane	Beverly	MA	01915	
Michael Cullen	Director	Chief Financial Officer, BIDMC	[redacted] Hayden Hollow	Plymouth	MA	02360	

Corporate Officer Info
PAGE 1 OF 2

Corporate Officers								
Name	Title 1	Title 2	Business Street	Business City	Business State	Business Zip	Business Phone	Business Fax
Nate Horwitz-Willis	Director	Founding Principal, Leliwop	719 Washington St #202	Boston	MA	02124	501-551-1778	781-352-6690
Michael Rowan	Director	Executive Vice President, Hospital and Ambulatory Services, BILH	20 University Road, Suite 700	Cambridge	MA	02138	617-278-8873	617-661-5365
Quan Pho	Director	Chief Pharmacy Officer, BILH	80 Wilson Way, Suite B	Westwood	MA	02090	781-352-6700	781-352-6610
Nicole Devita	Director	Chief Operating Officer, BILH	701 Edgewater Park Drive	Wakefield	MA	01880	978-236-1655	617-754-1040
Richard Fernandez	Director	President, BID-Milton	199 Reedsdale Rd	Milton	MA	02186	617-313-1353	617-313-1565
Efstathios (Stathis) Antoniades	Director	Chief Operating Officer, LHMC	41 Mall Rd	Burlington	MA	01805	781-744-8594	781-744-2785
Connie Woodworth	Director	Vice President of Finance, Beverly & Addison Gilbert Hospitals	85 Herrick St	Beverly	MA	01915	978-816-2587	978-921-7071
Michael.Cullen	Director	Chief Financial Officer, BIDMC	80 Wilson Way, Suite B	Westwood	MA	02090	781-352-6700	781-352-6610

4F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy* **or** ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Care Fusion Rx

Physical Address: 7052 Orangewood Avenue A8

Mailing Address: Same

City: Garden Grove State: CA Zip Code: 92841

Telephone: (855) 422-7379 Fax: (855) 733-9898

Toll Free Number: (855) 422-7379 (Required per NAC 639.708)

E-mail: contact@carefusionrx.com Website: www.carefusionrx.com

Managing Pharmacist: James Markis, Pharm D License Number: 58534 (CA)

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: Home Infusion	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

JM

Original Signature of Person Authorized to Submit Application, no copies or stamps

James Markis, Pharm D

Print Name of Authorized Person

6/23/21

Date

Board Use Only Date Processed:_____ Amount: 500 Check #1185041361693

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Care Fusion Rx Holdings, LLC

Mailing Address: 7052 Orangewood Avenue A8

City: Garden Grove State: CA Zip: 92841

Telephone: (855) 422-7379 Fax: (855) 733-9898

Contact Person: James Markis, Pharm D

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Wayne Nash [redacted]207th Street East, Bradenton, FL 34211
Name Address

b) Stephen Roberts [redacted] Commissioners Drive, Jacksonville, FL 32224
Name Address

c) Thomas Dervin [redacted]Seward Street, Omaha, NE 68154
Name Address

d) Ryan Ferguson [redacted] Shelter Bay Avenue, Mill Valley, CA 94941
Name Address

2) Provide the number of shares issued by the corporation. 3,000

3) What was the price paid per share? $1,000

4) What date did the corporation actually receive the cash assets? January 6, 2020

5) Provide a copy of the corporation's stock register evidencing the above information
Please see LLC Agreement Schedule A

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: N/A %:

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5:00 pm Saturday Closed am pm

Sunday Closed am pm 24 Hours On-Call

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Wayne Nash, President

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, James Markis, Pharm D

Responsible Person of Care Fusion Rx

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

James Markis, Pharm D

Print Name of Authorized Person

6/23/21

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
) ss.
Orange COUNTY)

I, James Markis, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge for Care Fusion Rx (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, James Markis, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

06/23/21

SUBSCRIBED AND SWORN TO
before me, a notary public this
___day of_____, 20___.

SEE ATTACHED DOCUMENT

NOTARY PUBLIC

CALIFORNIA JURAT GOVERNMENT CODE § 8202

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

State of California

County of Orange

Subscribed and sworn to (or affirmed) before me on this 23rd day of June, 2021, by

(1) James Anthony Markis

(and (2) _____),

Name(s) of Signer(s)

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

AMY BELTRAN
Notary Public - California
Orange County
Commission # 2349722
My Comm. Expires Mar 2, 2025

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Affidavit for Out of State Pharmacy License

Document Date: 6/23/2021 Number of Pages: 2

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

Transmitting Controlled Substance Prescription Data

N/A

Pursuant to NAC 639.926, pharmacies and dispensing practitioners that dispense controlled substances listed in schedule II, III or IV are required to submit data to the Board each week; however, we highly encourage dispensers to submit data on a nightly basis when possible. If a dispenser has not dispensed any controlled substances for the required time period, the dispenser is required to submit a zero reporting transmission.

The Nevada State Board of Pharmacy contracts with Appriss to manage the data collection for the Nevada Prescription Monitoring Program (PMP). For information to register and submit data please visit: http://bop.nv.gov. Click Links, click Prescription Monitoring Program, click Dispenser Guide.

If you have any questions or need additional information, please email: pmp@pharmacy.nv.gov

Cure Fusion Rx does not stock or dispense any controlled medications

SCHEDULE A[1]

Effective as of June 15, 2020

Member	Units	Class	Capital Account
Wayne Nash [redacted]207th Street East Bradenton, Florida 34211	1,230	Founder	$1,230,000
Stephen Roberts [redacted]Commissioners Drive Jacksonville, Florida 32224	1,230	Class A Units	$1,230,000
Ryan Ferguson [redacted] Shelter Bay Avenue Mill Valley, California 94941	210	Founder	$210,000
Thomas Dervin [redacted] Seward Street Omaha, Nebraska 68154	210	Founder	$210,000
SJL Holdings, Inc. c/o Michael Mindlin [redacted] Dudley Road Newton, Massachusetts 02459	60	Founder	$60,000
James Markis [redacted]Gates Avenue, Unit B Redondo Beach, California 90278	60	Founder	$60,000
TOTAL	3,000		$3,000,000

[1] Schedule A reflects aggregate funding commitments. It is anticipated that a portion of the amounts listed above will be funded initially with a commitment for the remaining amounts to be funded over a certain period of time.

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO. PHY 57710

ISSUE DATE AUGUST 11, 2020

CARE FUSION RX

7052 ORANGEWOOD AVE A8
GARDEN GROVE CA 92841

The above is licensed with the State Board of Pharmacy as a Limited Liability Company.

LIMITED LIABILITY COMPANY
JAMES ANTHONY MARKIS PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL AUGUST 01, 2021

RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

8/11/20
8/11/20

----- POST IN PUBLIC VIEW -----

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CARE FUSION RX, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CARE FUSION RX, LLC" WAS FORMED ON THE TWENTY-SIXTH DAY OF NOVEMBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7722154 8300

SR# 20210563790

Authentication: 202563235

Date: 02-22-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 11, 2021

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: JAMES ANTHONY MARKIS

License Type: PHARMACIST

License Number: RPH 58534

Status: ACTIVE

Issue Date: 08/08/2006

Expiration Date: 12/31/2021

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3141
Pharmacy.PublicRecords@dca.ca.gov

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 24, 2021

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: CARE FUSION RX

License Type: PHARMACY

License Number: PHY 57710

Status: ACTIVE

Issue Date: 08/11/2020

Expiration Date: 08/01/2021

Address of Record: 7052 ORANGEWOOD AVENUE A8 GARDEN GROVE, CA 92841

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3141
Pharmacy.PublicRecords@dca.ca.gov

4G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☒ *Partnership - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: AMERICAN HEALTHCARE AND PHARMACY DBA COLTON PHARMACY

Physical Address: 518 W VALLEY BLVD, COLTON CA 92324

Mailing Address: 518 W VALLEY BLVD

City: COLTON State: CA Zip Code: 92324

Telephone: 909-422-0444 Fax: 909-422-0459

Toll Free Number (877) 826-5866 (Required per NAC 639.708)

E-mail: coltonpharmacy99@gmail.com Website: _____

Managing Pharmacist: DEVI PATEL License Number: RPH 76510

TYPE OF PHARMACY AND	Yes/No	SERVICES PROVIDED	Yes/No
Retail	☒ ☐	Off-site Cognitive Services	☐ ☒
Hospital (# beds____)	☐ ☒	Parenteral **	☐ ☒
Internet	☐ ☒	Parenteral (outpatient)	☐ ☒
Nuclear	☐ ☒	Outpatient/Discharge	☐ ☒
Ambulatory Surgery Center	☐ ☒	Mail Service	☒ ☐
Community	☐ ☒	Long Term Care	☐ ☒
Other: _____	☐ ☒	Sterile Compounding **	☐ ☒
		Non Sterile Compounding	☐ ☒
All boxes must be checked		Mail Service Sterile Compounding **	☐ ☒
For the application to be complete		Other Services: _____	☐ ☒

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Hejal n patel
Original Signature of Person Authorized to Submit Application, no copies or stamps

HEJALIN PATEL
Print Name of Authorized Person

04/30/2021
Date

Board Use Only Date Processed:_____ Amount: 500
mo # 192532771071

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General X Limited _____

Partnership Name: AMERICAN HEALTHCARE AND PHARMACY INC

Mailing Address: 518 W VALLEY BLVD

City: COLTON State: CA Zip Code: 92324

Telephone Number: 909 422 0644 Fax Number: 909 422 0459

Contact Person: HEJALIN PATEL

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
HEJALIN PATEL	G	40%
GOPAL SOJITRA	G	20%

List names of 4 largest partners and percentage of ownership:

Name: BADAL SATASIA %: 20%

Name: PIYUSH SAKHA RELIYA %: 20%

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: NIA %: NIA

Name: NIA %: NIA

Name: NIA %: NIA

Hours of Operation for the pharmacy:

Monday thru Friday 9:30 am 6:00 pm Saturday 9:00 am 1:00 pm

Sunday CLOSED am _____ pm 24 Hours NIA

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, HEJALIN PATEL

Responsible Person of AMERICAN HEALTHCARE AND PHARMACY INC hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Heji. patel

Original Signature of Person Authorized to Submit Application, no copies or stamps

HEJALIN PATEL

Print Name of Authorized Person

04/30/2021

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
) ss.
Riverside COUNTY)

I, HEJALIN PATEL, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO for AMERICAN HEALTHCARE AND PHARMACY INC DBA COLTON PHARMACY (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, HEJALIN PATEL, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Hejalin Patel
Name HEJALIN PATEL

SUBSCRIBED AND SWORN TO before me, a notary public this 17th day of MAY, 2021.

Priti B. Patel
NOTARY PUBLIC

PRITI B PATEL
Notary Public - California
Riverside County
Commission # 2352663
My Comm. Expires Apr 17, 2025

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 55977
RECEIPT NO. 03020351

VALID UNTIL DECEMBER 01, 2021

COLTON PHARMACY
518 W VALLEY BLVD
COLTON CA 92324

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

10/30/20
10/30/20 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19)

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	AMERICAN HEALTHCARE AND PHARMACY INC
File Number:	C4062877
Registration Date:	09/11/2017
Entity Type:	DOMESTIC STOCK CORPORATION
Jurisdiction:	CALIFORNIA
Status:	ACTIVE (GOOD STANDING)

As of April 29, 2021 (Certification Date), the entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 30, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: R44AAVR

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at *bebizfile.sos.ca.gov/certification/index*.

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

HEJALIN PATEL → CEO

GOPAL SOJITRA → CFO

PIYUSH SAKHARELIYA → SECRETARY

BADAL SATASIA → DIRECTOR

----- Forwarded Message -----
From: Pharmacy PublicRecords@DCA <pharmacy.publicrecords@dca.ca.gov>
To: Oleg Piller <rxhelp911@yahoo.com>
Sent: Monday, May 17, 2021, 09:14:38 AM PDT
Subject: RE: Colton Pharmacy Letter of Good standing needed

Hello!

Please find the requested license verification attached. Per your request, the verification will be emailed and not mailed.

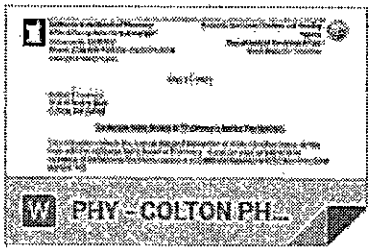
Thank you,

Public Records Analyst

California State Board of Pharmacy

(916) 518-3141 | FAX (916) 574-8617 | www.pharmacy.ca.gov

Be Aware and Take Care: Talk to your Pharmacist!



California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 17, 2021

Colton Pharmacy
518 W Valley Blvd
Colton, CA 92324

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: COLTON PHARMACY

License Type: PHARMACY

License Number: PHY 55977

Status: ACTIVE

Issue Date: 12/08/2017

Expiration Date: 12/01/2021

Address of Record: 518 W VALLEY BLVD COLTON, CA 92324

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3141
Pharmacy.PublicRecords@dca.ca.gov

Visit our website at www.pharmacy.ca.gov

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy Suite 206,

Reno, NV 89521

Re: Application for Out of State Pharmacy License

Hello,

We, American Healthcare and Pharmacy Inc DBA Colton Pharmacy is interested in opting for Nevada State Board of Pharmacy License for our pharmacy in California.

Please see attached application package along with all necessary documents for application package.

Please review them and let me know if you need any additional information and you can reach us at coltonpharmacy99@gmail.com or 909-422-0444.

Thanks

Hejalin Patel

CEO

American Healthcare and Pharmacy Inc



Candy Nally

From: Candy Nally
Sent: Wednesday, December 16, 2020 10:16 AM
To: 'hhsshapiropharmacy@hcmed.org'
Subject: Toll Free Number Required

Name: HCMC Shapiro Pharmacy

We are in receipt of your out-of-state pharmacy application. Nevada law NAC 639.708 requires a toll free number for all out-of-state pharmacies. Please provide the required toll free number. The application cannot be placed on an agenda until the 800 number has been provided.

If you have any questions, please feel free to contact us.

Thanks,

Candy M. Nally
Licensing Specialist
Nevada State Board of Pharmacy
cnally@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

Maria Herrera

From: colton pharmacy <coltonpharmacy99@gmail.com>
Sent: Thursday, May 27, 2021 7:58 AM
To: Maria Herrera
Subject: Re: Nevada Out-of-State Application- American Healthcare and Pharmacy dba Colton Pharmacy
Attachments: Certificate of Status.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Hi Maria,
Good morning!
Thank you for your review.
Here is our toll free number : (877) 826-5866
~~Please see attached Certificate of Corporate Status date d April 2021.~~

Please let me know if you need any additional information.

Thanks
Hejalin

On May 27, 2021, at 7:46 AM, Maria Herrera <m.herrera@pharmacy.nv.gov> wrote:

We are in receipt of your Out-of-State application for a pharmacy license. Nevada law NAC 639.708 requires a toll free number for all Out-of-State pharmacies, please provide the required toll free number. The application can't be placed on an agenda for approval until receipt of the 800 number. The items below have also become outdated and will need to be update.

- Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate of Corporate status is obtained from the Secretary of State's office in the State where incorporated. This Certificate of Corporate status must be dated within the last 6 months.

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
775-850-1440
m.herrera@pharmacy.nv.gov

4H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8* ☐ *Partnership - Pages 1,2,6,8*

☑ *Non Publicly Traded Corporation – Pages 1,2,4,8* ☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: LIFELINE SPECIALTY PHARMACY

Physical Address: 3233 CORPORATE CT. ELLICOTT CITY MD 21043

Mailing Address: 3233 CORPORATE CT

City: ELLICOTT CITY State: MD Zip Code: 21043

Telephone: 410-203-1010 Fax: 410-203-1515

✓ Toll Free Number: 1-833-454-3354 (Required per NAC 639.708)

E-mail: INFOELIFELINESPECIALTYPHARMACY.COM Website: WWW.LIFELINESPECIALTYPHARMACY.COM

Managing Pharmacist: DEEKSHITH KUMAR R KATTA License Number: 24194

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral **
☐	☑ Internet	☑	☐ Parenteral (outpatient)
☐	☑ Nuclear	☑	☐ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☑	☐ Other: SPECIALTY PHARMACY	☐	☑ Sterile Compounding **
		☐	☐ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☑	☐ Other Services: SPECIALTY MEDICATIONS

****If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

RAJESHWER R PINGILI
Print Name of Authorized Person

04/13/2021
Date

Board Use Only Date Processed:_____ Amount: 500
Check # 3011683326-6

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: MARYLAND

Parent Company if any: VDNR PHARMACY LLC

Mailing Address: 3233 CORPORATE CT.

City: ELLICOTT CITY State: MD Zip: 21043

Telephone: 410-203-1010 Fax: 410-203-1515

Contact Person: RAJESHWER R PINGILI

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) RAJESHWER R PINGILI [redacted] HONEY LOCUST CT ELLICOTT CITY MD 21042
Name Address

b) DEEKSHITH KUMAR R KATTA [redacted] GAITHER HOLLOW CT ELLICOTT CITY MD 21043
Name Address

c) RRP SPOUSAL TRUST [redacted] HONEY LOCUST CT ELLICOTT CITY MD 21042
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 10,000

3) What was the price paid per share? $40

4) What date did the corporation actually receive the cash assets? $400000

5) Provide a copy of the corporation's stock register evidencing the above information ATTACHED.

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday 10 am 1 pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, RAJESHWER R PINGILI

Responsible Person of UDNR PHARMACY LLC DBA LIFELINE SPECIALTY PHARMACY hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

RAJESHWER R PINGILI
Print Name of Authorized Person

04/13/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF MARYLAND)
) ss.
HOWARD COUNTY)

I, RAJESHWER R PINGILI, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the RESPONSIBLE PERSON for LIFELINE SPECIALTY PHARMACY (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, RAJESHWER R PINGILI, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

RAJESHWER R PINGILI
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
16th day of April, 2021.

NOTARY PUBLIC

JOSE JESUS GONZALEZ
NOTARY PUBLIC
PRINCE GEORGE'S COUNTY, MD
MY COMMISSION EXPIRES JUNE 10, 2023

VDNR Pharmacy LLC
Membership Ledger

Date	Unit Holder Name	Units issued	Price paid	Price Per unit
9/12/2017	Rajeshwer R. Pingili	500	$ 20,000.00	$ 40.00
9/12/2017	Deekshith K. Katta	1500	$ 60,000.00	$ 40.00
9/12/2017	RRP SPOUSAL TRUST	8000	$ 320,000.00	$ 40.00

106963

State of Maryland

DEPARTMENT OF HEALTH

SIGNATURE OF BEARER

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Lifeline Specialty Pharmacy
IS A REGISTERED Active
License Expiration Date
Pharmacy Waiver 05/31/2022

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
PW0513	05/31/2022

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

STATE OF MARYLAND
Department of Assessments and Taxation

I, MICHAEL L. HIGGS OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO LIMITED LIABILITY COMPANIES , OR THE RIGHTS OF LIMITED LIABILITY COMPANIES TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT VDNR PHARMACY LLC (W18259614) , REGISTERED SEPTEMBER 11, 2017, IS A LIMITED LIABILITY COMPANY EXISTING UNDER AND BY VIRTUE OF THE LAWS OF THE STATE OF MARYLAND, AND THAT THE LIMITED LIABILITY COMPANY IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING TO TRANSACT BUSINESS.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS APRIL 16, 2021.

Michael L. Higgs
Director

301 West Preston Street, Baltimore, Maryland 21201
Telephone Baltimore Metro (410) 767-1340 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: dnNceHmd60WJZN_HR4YilA
To verify the Authentication Code, visit http://dat.maryland.gov/verify

MARYLAND
Department of Health

Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Dennis R. Schrader, Secretary

MARYLAND BOARD OF PHARMACY
4201, Patterson Avenue, Baltimore, Maryland 21215-2299
Jennifer Hardesty, Board President • Deena Speights-Napata, Executive Director

Maryland Board of Pharmacy
ESTABLISHMENT VERIFICATION OF GOOD STANDING

NAME OF ESTABLISHMENT: Lifeline Specialty Pharmacy
3233 Corporate Court
Ellicott City, MD 21043

TYPE OF REGISTRATION ISSUED: **Pharmacy Waiver**

LICENSE NUMBER: **PW0513**

ORIGINAL ISSUANCE DATE: 11/02/2017

EXPIRATION DATE: 05/31/2022

CURRENT STATUS: Active X Non-Renewed ___ Closed ___ Revoked ___

GOOD STANDING: Yes X No ___

HAS ESTABLISHMENT BEEN FOUND GUILTY OF ANY VIOLATIONS FOR WHICH DISCIPLINARY ACTION WAS TAKEN? Yes _____ No X

SIGNATURE: Deena Speights-Napata

Deena Speights-Napata, M.A.

Executive Director

Date: 04/30/2021

410-764-4755 • Fax 410-358-6207 • Toll Free 800-542-4964
DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: www.dhmh.maryland.gov/pharmacy

4l

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☑ *Partnership - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Gretna Xpress Pharmacy

Physical Address: 1620 Belle Chasse Hwy Ste A Terrytown, LA 70056

Mailing Address: 1620 Belle Chasse Hwy Ste A

City: Terrytown State: LA Zip Code: 70056

Telephone: 504-368-5977 Fax: n/a

Toll Free Number: _____ (Required per NAC 639.708)

E-mail: GretnaXpress1@gmail.com Website: n/a

Managing Pharmacist: Jimmy R. Donald Jr. License Number: PST.020420

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☐	☑ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☑	☐ Other: Non-Resident Pharmacy	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Michaela Capello

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michaela Capello

Print Name of Authorized Person

5/15/21

Date

Board Use Only Date Processed:_____ Amount: $500 MO # 19-252798733

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Louisiana

Parent Company if any: _____

Mailing Address: 1620 Belle Chasse Hwy Ste A

City: Terrytown State: LA Zip: 70056

Telephone: 504-368-5977 Fax: _____

Contact Person: Michaela Capello

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Michaela Capello [redacted] East Riverside Dr [redacted] Austin TX 78741
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 200

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: n/a %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday closed am _____ pm

Sunday closed am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: n/a

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Michaela Capello
Address: [redacted] East Riverside Dr [redacted] Austin, TX 78741
Phone: [redacted]

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Jimmy R. Donald Jr.

Responsible Person of Gretna Xpress Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jimmy R. Donald Jr.
Print Name of Authorized Person

20 May 21
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Florida)
) ss.
Palm Beach COUNTY)

I, Michaela Capello, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager for Gretna Xpress Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Michaela Capello, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Michaela Capello
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
15 day of May, 2021.

NOTARY PUBLIC

CHRISTINA GIANATIEMPO
Notary Public-State of Florida
Commission # GG 948951
My Commission Expires
January 20, 2024

State of Louisiana Secretary of State

COMMERCIAL DIVISION
225.925.4704

Fax Numbers
225.932.5317 (Admin. Services)
225.932.5314 (Corporations)
225.932.5318 (UCC)

Name	Type	City	Status
GRETNA XPRESS PHARMACY LLC	Limited Liability Company	GRETNA	Active

Previous Names

Business: GRETNA XPRESS PHARMACY LLC
Charter Number: 42822123K
Registration Date: 10/6/2017

Domicile Address

1620 BELLE CHASSE HIGHWAY SUITE A
GRETNA, LA 70056

Mailing Address

1620 BELLE CHASSE HIGHWAY SUITE A
GRETNA, LA 70056

Status

Status: **Active**
Annual Report Status: **In Good Standing**
File Date: 10/6/2017
Last Report Filed: 3/17/2021
Type: Limited Liability Company

Registered Agent(s)

Agent: MICHAELA CAPPELLO
Address 1: 1620 BELLE CHASSE HIGHWAY SUITE A
City, State, Zip: GRETNA, LA 70056
Appointment Date: 4/21/2021

Officer(s)

Additional Officers: No

Officer: MICHAELA CAPPELLO
Title: Manager, Member
Address 1: 1620 BELLE CHASSE HIGHWAY
Address 2: SUITE A
City, State, Zip: GRETNA, LA 70056

Amendments on File (2)

Description	Date

Domestic LLC Agent/Domicile Change	4/21/2021
Appointing, Change, or Resign of Officer	5/6/2021

Print

LOUISIANA BOARD of PHARMACY

3388 Brentwood Drive ~ Baton Rouge, LA 70809-1700
www.pharmacy.la.gov

PHARMACY PERMIT

Permit Owner: Gretna Xpress Pharmacy LLC

This is to certify that the Pharmacy listed hereon is duly permitted to operate a PHARMACY in Louisiana for the referenced period at the address noted:

Gretna Xpress Pharmacy
1620 Belle Chasse Hwy Ste A
Gretha, LA 70056

Permit Number: PHY.007891-IR
Effective Date: 01/01/2021
Expiration Date: 12/31/2021

PHY 2021

PERMIT MUST BE DISPLAYED IN PHARMACY
THIS PERMIT IS NOT TRANSFERABLE
A change in ownership or relocation of the pharmacy requires a new permit

Carl W. Aron
President

Louisiana Board of Pharmacy

3388 Brentwood Drive – Baton Rouge, LA 70809-1700

Controlled Dangerous Substance (CDS) License

Shall be Publicly Displayed at All Times, and Used ONLY in Place of Business Indicated Below

This is to certify that the person or firm listed below has been duly licensed with the Louisiana Board of Pharmacy, according to the requirements of the Uniform Dangerous Substances Law, Title 40, Chapter 4, Part X, Louisiana Revised Statutes 1950 as amended, to either manufacture, distribute, dispense, prescribe, and/or conduct research with Controlled Dangerous Substances in Schedules 1, 2, 2N (noncarcotic), 3, 3N (noncarcotic), 4, and 5 Section 964 of said act or as otherwise specified on the original application.

Gretna Xpress Pharmacy
1620 Belle Chasse Hwy Ste A
Gretha, LA 70056

CDS License - Pharmacy

Credential Number: CDS.054700-PHY
Expiration Date: 12/31/2021
Approved Schedules and/or Drugs:

1:	No	**3:**	Yes
2:	Yes	**3N:**	Yes
2N:	Yes	**4:**	Yes
		5:	Yes

11ZOO



The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
Gretna Xpress Pharmacy	1620 Belle Chasse Hwy Ste A Terrytown, LA 70056-7057

Credential Information with supervision

License	License Type	Issue Date	Expiration Date	Status	Pharmacist In Charge
PHY.007891-IR	Pharmacy - Community ~ Independent	04/22/2019	12/31/2021	Current, without restriction or limitation	Jimmy R. Donald Jr.

List of Current Employees

Name	License	License Type	Expiration Date	Status
Jimmy R. Donald Jr.	PST.020420	Pharmacist	12/31/2021	ACTIVE

Generated on: 5/5/2021 7:00:00 AM

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name

Name
Jimmy R. Donald Jr.

Credential Information

License	License Type	Issue Date	Expiration Date	Status
PST.020420	Pharmacist	01/02/2014	12/31/2021	Current, without restriction or limitation

Education

School	Graduation Date	Degree
Xavier University of Louisiana	08/03/2013	PharmD

Current Employment

Name	License	License Type	Expiration Date	Status
Greenbrier Behavioral Health	PHY.005542-HOS	Pharmacy - Hospital Inpatient	12/31/2021	ACTIVE
Gretna Xpress Pharmacy	PHY.007891-IR	Pharmacy - Community ~ Independent	12/31/2021	ACTIVE

Prior Board Orders (may or may not be disciplinary in nature)

File Number	Status	Date Recieved	Date Closed	Resolution
2008-750	CLOSED	12/09/2008	08/05/2009	Board authorized issuance of pharmacy intern registration, then suspended it for five years and stayed the execution thereof, and then placed the registration on probation for five years, effective 08-05-2009, subject to certain terms as enumerated in the consent agreement.
2009-750	CLOSED	08/05/2009	12/12/2012	Probationary period scheduled to conclude on 08-05-2014; however, terminated early by Board on 12-12-2012.
2012-278	CLOSED	10/03/2012	12/12/2012	Board granted request for modification of previously-imposed probationary terms; all terms of probation removed, and intern registration returned to active and unrestricted status, effective 12-12-2012.

Generated on: 5/5/2021 7:00:40 AM

4J

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* **PH**_____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Medpack LLC

Physical Address: 5923 Strickland Ave. Brooklyn, NY 11234

Mailing Address: 5923 Strickland Ave.

City: Brooklyn State: NY Zip Code: 11234

Telephone: 347-506-1000 Fax: 718-975-7755

√ Toll Free Number: 844-575-2500 (Required per NAC 639.708)

E-mail: jb@medpackrx.com Website: www.medpackrx.com

Managing Pharmacist: Joseph Anthony Bressi License Number: 050874

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☑	☐ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Martin Kleinman
Original Signature of Person Authorized to Submit Application, no copies or stamps

Martin Kleinman
Print Name of Authorized Person

5/12/21
Date

Board Use Only Date Processed:_____ Amount: 500 (cc)

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: New York

Parent Company if any: _____

Mailing Address: 5923 Strickland Ave.

City: Brooklyn State: NY Zip: 11234

Telephone: 347-506-1000 Fax: 718-975-7755

Contact Person: Joseph Anthony Bressi

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Martin Kleinman (Name) 5923 Strickland Ave. Brooklyn, NY 11234 (Address)

b) Jeffrey Edelman (Name) 5923 Strickland Ave. Brooklyn, NY 11234 (Address)

c) _____ (Name) _____ (Address)

d) _____ (Name) _____ (Address)

2) Provide the number of shares issued by the corporation. 0

3) What was the price paid per share? 0

4) What date did the corporation actually receive the cash assets? 06/19/2014

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 5 pm Saturday Closed am Closed pm

Sunday Closed am Closed pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Martin Kleinman

Responsible Person of Medpack LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Martin Kleinman
Print Name of Authorized Person

5/12/21
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF NY)
) ss.
Kings COUNTY)

I, Martin Kleinman, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member for Medpack LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Martin Kleinman, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
13 day of May, 2021.

NOTARY PUBLIC

MICHELE FALOTICO
Notary Public, State of New York
No. 01FA6030014
Qualified in Queens County
Commission Expires August 30, 2023

List of all Owner, Officers, Directors:

Title: Managing Member

Name: Martin Kleinman

Address: 5923 Strickland Ave. Brooklyn, NY 11234

D.O.B: [redacted]

RPH: No

Ownership: 86.7%

Title: Member

Name: Jeffrey Edelman

Address: 5923 Strickland Ave. Brooklyn, NY 11234

D.O.B: [redacted]

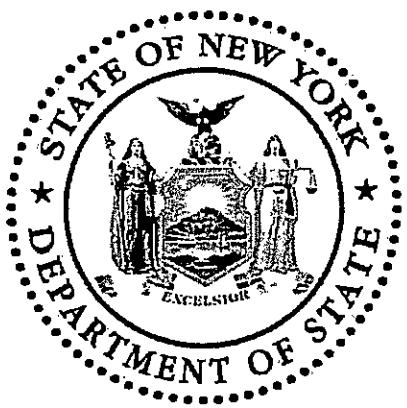
RPH: No

Ownership: 13.3%

STATE OF NEW YORK

DEPARTMENT OF STATE

I hereby certify that the annexed copy has been compared with the original document in the custody of the Secretary of State and that the same is true copy of said original.



WITNESS my hand and official seal of the Department of State, at the City of Albany, on March 03, 2014.

Anthony Giardina
Executive Deputy Secretary of State

Rev. 06/07

ARTICLES OF ORGANIZATION
OF
MEDPACK LLC

Under Section 203 of the Limited Liability Company Law

FIRST: The name of the limited liability company is:

MEDPACK LLC

SECOND: The county, within this state, in which the office of the limited liability company is to be located is KINGS.

THIRD: The Secretary of State is designated as agent of the limited liability company upon whom process against it may be served. The address within or without this state to which the Secretary of State shall mail a copy of any process against the limited liability company served upon him or her is:

THE LIMITED LIABILITY COMPANY
171 Kings Highway
Brooklyn, NY 11223

I certify that I have read the above statements, I am authorized to sign this Articles of Organization, that the above statements are true and correct to the best of my knowledge and belief and that my signature typed below constitutes my signature.

Kimberly Kline, Organizer (signature)

Kimberly Kline , ORGANIZER
80 STATE ST.
ALBANY, NY 12207

Filed by:
Richard A. Ross, Esq.
100 Garden City Plaza
Suite 408
Garden City, NY 11530

CORPORATION SERVICE COMPANY (45)

DRAWDOWN

CUSTOMER REF# 028645kxk

FILED WITH THE NYS DEPARTMENT OF STATE ON: 03/03/2014
FILE NUMBER: 140303010141; DOS ID: 4537417

New York State Department of State

Division of Corporations

PLEASE PRINT THIS E-MAIL FOR YOUR RECORDS.

Thank you for submitting your business entity filing through the e-Corp Filing System. The Articles of Organization has been filed by the Department of State.

Attached are the filing receipt and related document(s) for the following business entity:

Dos ID: 4537417

Business Name: MEDPACK LLC

County: KINGS

Filing Date: 03/03/2014

Biennial Statement Due: 03/03/2016

E-Mail Address: nycorponline@cscinfo.com

Please retain this email and attachment(s) for your records. The Department of State will not re-send this email. Please note the Department of State does not issue duplicate filing receipts.

The domestic limited liability company is required to file a Biennial Statement with the Department of State every two years pursuant to § 301 LLC. The Department of State will send an email reminder notice when the Biennial Statement for your domestic limited liability company is due. The notice will be sent to the email address indicated above. You may update the email address by accessing the Department of State's Biennial Statement Email Address Notification website at www.email.ebiennial.dos.ny.gov.

Instructions for Certificates of Correction and Certificates of Amendment are available on the Department of State's website at http://www.dos.ny.gov/corps/dom_llcfile.html. If you have any questions, please contact the Division of Corporations at eCorps@dos.ny.gov.

N.Y.S. DEPARTMENT OF STATE
DIVISION OF CORPORATIONS AND STATE RECORDS ALBANY, NY 12231-0001

ONLINE FILING RECEIPT

ENTITY NAME: MEDPACK LLC

DOCUMENT TYPE: ARTICLES OF ORGANIZATION (DOM. LLC) COUNTY: KING

FILED:03/03/2014 DURATION:********** CASH#:140303010141 FILE#:140303010141
DOS ID:4537417

FILER:

RICHARD A. ROSS, ESQ.
100 GARDEN CITY PLAZA
SUITE 408
GARDEN CITY, NY 11530

EXIST DATE
03/03/2014

ADDRESS FOR PROCESS:

THE LIMITED LIABILITY COMPANY
171 KINGS HIGHWAY
BROOKLYN, NY 11223

REGISTERED AGENT:

The limited liability company is required to file a Biennial Statement with the Department of State every two years pursuant to Limited Liability Company Law Section 301. Notification that the Biennial Statement is due will only be made via email. Please go to www.email.ebiennial.dos.ny.gov to provide an email address to receive an email notification when the Biennial Statement is due.

SERVICE COMPANY: CORPORATION SERVICE COMPANY-45
SERVICE CODE: 45

FEE:	210.00
FILING:	200.00
TAX:	0.00
PLAIN COPY:	0.00
CERT COPY:	10.00
CERT OF EXIST:	0.00

PAYMENTS	210.00
CHARGE	0.00
DRAWDOWN	210.00

DOS-1025 (04/2007)

028645KXK

Authentication Number: 1403030159 To verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2020-23

SUPERVISING PHARMACIST
JOSEPH BRESSI

THIS IS TO CERTIFY

MEDPACK LLC.
5923 STRICKLAND AVENUE
BROOKLYN, NY 11234

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JUNE, 2020.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MAY, 2023.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

032803

Kimberly A. Leonard
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

NYSED.gov

OP OFFICE OF THE PROFESSIONS

Office of the Professions

Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

Pharmacy Establishment Information *

03/04/2021

Type : PHARMACY
Legal Name : MEDPACK LLC.
Trade Name :
Street Address :
5923 STRICKLAND AVENUE
BROOKLYN, NY 11234-0000

Registration No : 032803
Date First Registered : 06/19/14
Registration Begins : 06/01/20
Registered through : 05/31/23
Supervisor : 050874 BRESSI JOSEPH
Establishment Status : ACTIVE
Successor : NONE

* Use of this online verification service signifies that you have read and agree to the terms and conditions of use. See HELP glossary for further explanations of terms used on this page.

- Use your browser's back key to return to establishment list.
- You may search to see if there has been recent disciplinary action against this registered establishment.

THE UNIVERSITY OF THE STATE OF NEW YORK

EDUCATION DEPARTMENT

BE IT KNOWN THAT

JOSEPH ANTHONY BRESSI

HAVING GIVEN SATISFACTORY EVIDENCE OF THE COMPLETION OF PROFESSIONAL AND OTHER REQUIREMENTS PRESCRIBED BY LAW IS QUALIFIED TO PRACTICE AS A

PHARMACIST

IN THE STATE OF NEW YORK

IN WITNESS WHEREOF THE EDUCATION DEPARTMENT GRANTS THIS LICENSE UNDER ITS SEAL AT ALBANY, NEW YORK THIS THIRTIETH DAY OF MARCH, 2006.

PRESIDENT OF THE UNIVERSITY
AND COMMISSIONER OF EDUCATION

LICENSE NUMBER
050874

DEPUTY COMMISSIONER
OFFICE OF THE PROFESSIONS

EXECUTIVE SECRETARY
STATE BOARD OF
PHARMACY

5647679

4K

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy or* ☑ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** 02367

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
LLC ☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Optum Pharmacy 701, LLC

Physical Address: 4100 S. Saginaw Street, Suite D, Flint, MI 48507

Mailing Address: 4100 S. Saginaw Street, Suite D

City: Flint State: MI Zip Code: 48507

Telephone: 810-768-9539 Fax: 800-550-6272

Toll Free Number: 855-427-4682 (Required per NAC 639.708)

E-mail: orxpharmlic@optum.com Website: https://specialty.optumrx.com/

Managing Pharmacist: Gregory A. Jonas License Number: 5301008622 (MI)

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☐ Retail	☐	☐ Off-site Cognitive Services
☐	☐ Hospital (# beds____)	☐	☐ Parenteral **
☐	☐ Internet	☐	☐ Parenteral (outpatient)
☐	☐ Nuclear	☐	☐ Outpatient/Discharge
☐	☐ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☐ Long Term Care
☑	☐ Other: Infusion (no compounding)	☐	☐ Sterile Compounding **
		☐	☐ Non Sterile Compounding
All boxes must be checked		☐	☐ Mail Service Sterile Compounding **
For the application to be complete		☑	☐ Other Services: Specialty; Infusion

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Karen Peterson

Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen Peterson, Secretary

Print Name of Authorized Person

05/04/2021

Date

Board Use Only Date Processed:_____ Amount: 500 check #1661766867

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Entity is an LLC - Formed in Delaware

Parent Company if any: OptumRx Administrative Services, LLC

Mailing Address: 1600 McConnor Parkway

City: Schaumburg State: IL Zip: 60173

Telephone: 763-321-2595 Fax: 844-377-0216

Contact Person: Cathy Winters

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) No individual owners
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A - entity is an LLC

3) What was the price paid per share? N/A - entity is an LLC

4) What date did the corporation actually receive the cash assets? N/A - entity is an LLC

5) Provide a copy of the corporation's stock register evidencing the above information
N/A - entity is an LLC

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:00am am 7:00 pm Saturday 9:00 am 3:00 pm

Sunday On call am On call pm 24 Hours On call

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Karen Peterson

Responsible Person of Optum Pharmacy 701, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Karen Peterson, Secretary
Print Name of Authorized Person

05/04/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Illinois)
) ss.
Cook COUNTY)

I, Karen Peterson, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary for Optum Pharmacy 701, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Karen Peterson, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Karen Peterson
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
5th day of May, 2021.

Maleta G. Beahan
NOTARY PUBLIC

Official Seal
Maleta G Beahan
Notary Public State of Illinois
My Commission Expires 03/06/2022

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTUM PHARMACY 701, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7571773 8300

SR# 20210626273

Authentication: 202590505

Date: 02-24-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

Optum Pharmacy 701, LLC

Officer, Director, and Ownership Information

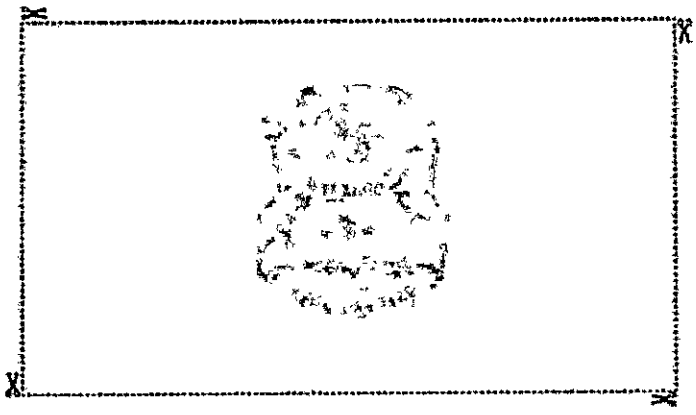
Officers:

Name	Title
Michael Zeglinski	Director
Jeffrey Grosklags	Director
Michael Zeglinski	President & CEO
Peter Gill	Treasurer
Karen Peterson	Secretary
Heather Lang	Assistant Secretary
David Oberg	Assistant Secretary
Timothy Langdon	Assistant Secretary

The pharmacy is wholly owned by:
Optum Pharmacy 701, LLC
FEIN: 84-2827343
1600 McConnor Parkway
Schaumburg, IL 60173
800-282-3232

The sole member of Optum Pharmacy 701, LLC is:
OptumRx Administrative Services, LLC
FEIN: 75-2578509
1600 McConnor Parkway
Schaumburg, IL 60173
800-282-3232

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



DIPLOMAT SPECIALTY PHARMACY
4100 S SAGINAW ST SUITE D
FLINT, MI 48507

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

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

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

P424577

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

BOARD OF PHARMACY

PHARMACY LICENSE

STERILE COMPOUNDING

DIPLOMAT SPECIALTY PHARMACY
4100 S SAGINAW ST SUITE D
FLINT, MI 48507

LICENSE NO.
5301008622

EXPIRATION DATE
5/21/2023

20174110658

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

Quarles & Brady LLP

300 N. LaSalle Street
Suite 4000
Chicago, Illinois 60654
312.715.5000
Fax 312.715.5155
www.quarles.com

Attorneys at Law in
Chicago
Indianapolis
Madison
Milwaukee
Minneapolis
Naples
Phoenix
Scottsdale
Tampa
Tucson
Washington, D.C.

Writer's Direct Dial: 312.715.5247
E-Mail: Laura.MacDonald@quarles.com

May 7, 2021

VIA UPS OVERNIGHT

Mr. Dave Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

RE: Change of Ownership and Name
Diplomat Specialty Pharmacy – Flint, MI
Nevada Pharmacy License No.: PH02367

Dear Dr. Wuest:

Please be advised that there will be an intracompany change of ownership that will result from a sale of assets related to the pharmacy in Flint, MI. Specifically, Diplomat Specialty Pharmacy will transfer assets to Optum Pharmacy 701, LLC. The ultimate indirect owner of the pharmacy will remain UnitedHealth Group Incorporated. **While not definitive, the anticipated effective date is on or about May 24, 2021.** The enclosed organizational chart shows the ownership structure after the intracompany transaction.

As a result of this intracompany change, there will be a change in the pharmacy's name, federal tax identification number, and officers. The pharmacy will discontinue use of any and all DBAs, and it will not use any DBAs going forward. However, the pharmacy's NPI, NCPDP number, and address will remain the same.

The application, supporting documents, and fees are enclosed. We request that this Change of Ownership and Name application for a Nevada non-resident pharmacy license be scheduled for consideration on the agenda for the July 14–15, 2021 Nevada Board of Pharmacy meeting. Please note that a change application is currently pending with the resident-state Michigan Board of Pharmacy. The parties will operate under a Power of Attorney to allow continued operations while applications are pending. Should you have any questions or require additional information, please contact me at 312-715-5247 or Laura.MacDonald@quarles.com. Thank you for your consideration.

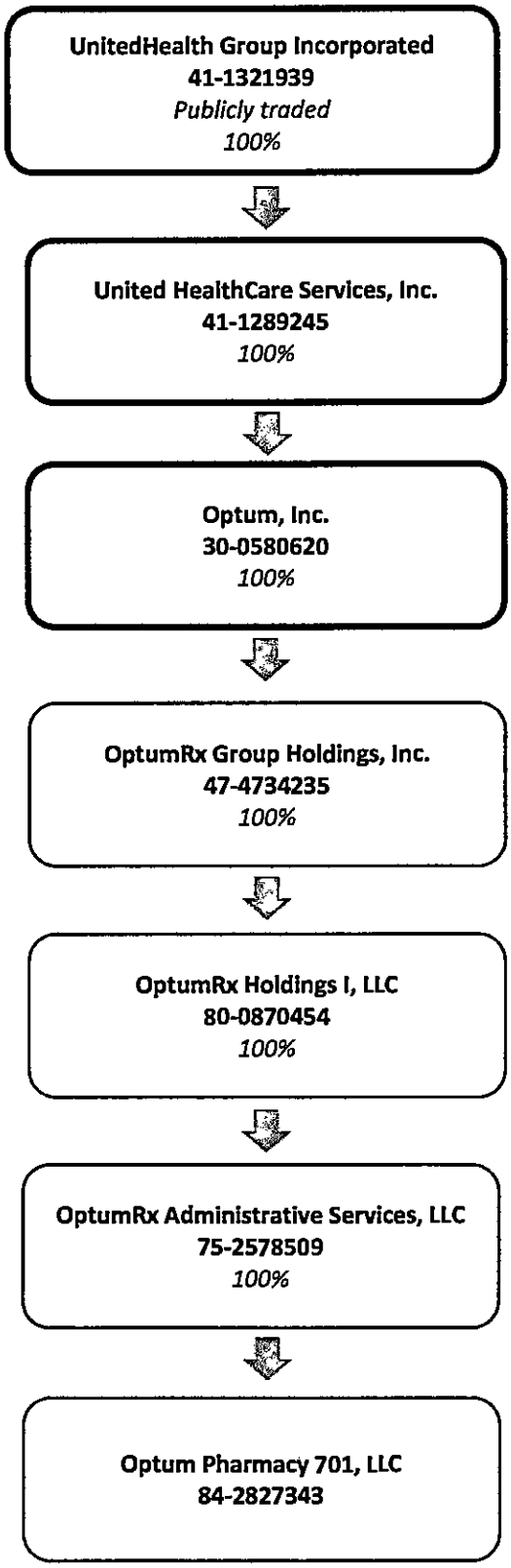
Very truly yours,

Laura MacDonald

Laura MacDonald

Enclosures

Organizational Chart After Intracompany Change of Ownership



GRETCHEN WHITMER
GOVERNOR

ORLENE HAWKS
DIRECTOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

VERIFICATION OF LICENSURE

MICHIGAN BOARD OF PHARMACY

VERIFICATION OF LICENSURE AS OF 06/08/2021

NAME: **Optum Pharmacy 701, LLC**
ADDRESS: 4100 S Saginaw St Suite D
Flint, MI 48507

STATUS: Active

LICENSE TYPE: Pharmacy License

LICENSE NUMBER: 5301008622

ORIGINAL DATE: 05/21/2007
EXPIRATION DATE: 05/21/2023
SPECIALTY:
None

EXAM DATE	EXAM TYPE	EXAM RESULTS
	None	

OPEN FORMAL COMPLAINTS

Yes

DISCIPLINARY ACTION	START DATE	END DATE
None		

Brian DeBano, Division Director
Bureau of Professional Licensing
Licensing Division
(517) 241-0199

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☑ *Partnership (Limited) - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: ReCept Pharmacy #75

Physical Address: 10412 Vista del Sol, Suite 1A El Paso TX 79925

Mailing Address: 1620 W. Northwest Hwy., Suite 100

City: Grapevine State: TX Zip Code: 76051

Telephone: (915) 533-0167 Fax: (915) 533-0168

Toll Free Number: (855) 201-3310 (Required per NAC 639.708)

E-mail: licensure@receptrx.com Website: www.receptrx.com

Managing Pharmacist: Miguel Estala, PharmD License Number: 42578

TYPE OF PHARMACY	**AND**	**SERVICES PROVIDED**
Yes/No		Yes/No
☒ ☐ Retail		☐ ☒ Off-site Cognitive Services
☐ ☒ Hospital (# beds_____)		☐ ☒ Parenteral **
☐ ☒ Internet		☐ ☒ Parenteral (outpatient)
☐ ☒ Nuclear		☐ ☒ Outpatient/Discharge
☐ ☒ Ambulatory Surgery Center		☒ ☐ Mail Service
☒ ☐ Community		☐ ☒ Long Term Care
☐ ☒ Other: _____		☐ ☒ Sterile Compounding **
		☐ ☒ Non Sterile Compounding
All boxes must be checked		☐ ☒ Mail Service Sterile Compounding **
For the application to be complete		☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Carmine DeNardo
Print Name of Authorized Person

4.13.2021
Date

Board Use Only Date Processed: _____ Amount: 500
Check # 0002362102

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General _____ Limited X

Partnership Name: ReCept Pharmacy, LP

Mailing Address: 1620 W. Northwest Hwy, Suite 100

City: Grapevine State: TX Zip Code: 76051

Telephone Number: (817) 572-0009 Fax Number: (817) 720-1039

Contact Person: Clarence Green

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
ReCept Pharmacy, LP	L	100%

List names of 4 largest partners and percentage of ownership: N/A

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership. N/A

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5:30 pm Saturday Closed am _____ pm

Sunday Closed am _____ pm 24 Hours On Call 24/7

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Carmine DeNardo

Responsible Person of ReCept Pharmacy, LP

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Carmine DeNardo
Print Name of Authorized Person

4.6.2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Texas)
) ss.
Tarrant COUNTY)

I, Carmine DeNardo, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO/President for ReCept Pharmacy, LP, dba ReCept Pharmacy #75 (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Carmine DeNardo, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
6 day of April, 2021.

NOTARY PUBLIC

Paula Sadovsky
My Commission Expires
03/06/2023
ID No. 131919441

Posted April 1, 2020



1620 W. Northwest Hwy., Suite 100
Grapevine, TX 76051
(p) 817.572.0009
(f) 817.572.0221
www.receptrx.com

RE: ReCept Pharmacy #1 – Disciplinary Action

To Whom It May Concern:

In a letter dated July 2, 2010, ReCept Pharmacy #1 received notice that the Texas State Board of Pharmacy was considering the institution of disciplinary actions against the pharmacy in response to an alleged violation with regard to a dispensing error that occurred in February 2009. ReCept Pharmacy was presented with several alternatives to settle the matter with the Board. One of the alternatives was an Agreed Board Order reprimanding the pharmacy license.

On August 11, 2010 the Texas State Board of Pharmacy entered Agreed Board Order (ABO) #H-09-27-B and reprimanded the pharmacy license issued to ReCept Pharmacy #1 (pharmacy license number 23060) for the period of August 11, 2010 to August 11, 2013. As part of the Agreed Board Order, ReCept Pharmacy, LP was required to develop and implement a Continuous Quality Improvement Program that includes peer review.

On October 7, 2010, ReCept Pharmacy #1 implemented its Continuous Quality Improvement Program. The purpose of the program is to identify and assess errors that occur in the pharmacy and then to make changes or adjustments in processes to prevent recurrences.

In addition, in April 2010 ReCept Pharmacy made several staffing changes at this location to include a change in Pharmacist-in-Charge, Staff Pharmacist and support staff.

As mentioned above, ReCept Pharmacy has introduced a Continuous Quality Improvement Program and Peer Review process to increase quality, improve workflow and reduce errors. Historically, the most common pharmacy error is dispensing the wrong drug (incorrect NDC). Through our Continuous Quality Improvement (CQI) Program, quality indicators are defined and measured on a continuous basis. All quality related events, even mistakes caught by the Pharmacists at final verification *before* ever reaching a patient, are reported through this process. This allows the Peer Review Committee, which consists of all key pharmacy personnel involved in dispensing prescriptions, to make adjustments in workflow and processes to help reduce future errors.

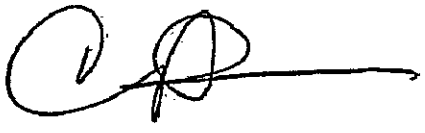
ReCept replaced a DOS-based dispensing system with a state-of-the-art pharmacy dispensing system. The new system is centrally maintained and provides our pharmacies with the latest technology for quality, workflow, and inventory management. Workflow and quality checks

ensure that NDC's are verified at two different points in the filling process. The filling Technician performs the first check and the verifying Pharmacist performs the final check.

At ReCept Pharmacy, quality and accuracy are the cornerstone of our business. We take pride in the services we provide to our customers and are continually seeking ways to further develop our operations.

If you should have any questions or would like further information on any of the programs and improvements presented in this response, please contact me at (817) 572-0009.

Sincerely,



Carmine DeNardo
CEO/President
ReCept Pharmacy, LP

AGREED BOARD ORDER #H-09-027-B

RE: IN THE MATTER OF RECEPT PHARMACY #1 (PHARMACY LICENSE #23060)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacy license number 23060 issued to ReCept Pharmacy #1, 800 8th Ave., Suite 130, Fort Worth, Texas 76104.

By letter dated July 2, 2010, the Texas State Board of Pharmacy gave preliminary notice to ReCept Pharmacy #1 of its intent to take disciplinary action with respect to pharmacy license number 23060 held by ReCept Pharmacy #1 as a result of an investigation which produced evidence indicating that ReCept Pharmacy #1 may have violated:

Section 565.001(a)(1), (2), (12) and (13); and Section 565.002(a)(3) and (6) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Subtitle J (2007);

Section 281.7(a)(12), (13) and (29)(A); Section 281.8(b)(4)(A); Section 291.31(1), (14) and (15); Section 291.32(c)(1)(E) and (F); Section 291.32(c)(2)(B), (C) and (D); and Section 295.3(b) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2009); and

Section 431.003; and Section 431.021(a), (b) and (r) of the Texas Food, Drug, and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. (2001), in that, allegedly:

COUNT

On or about February 27, 2009, Randy Warren Faulk, while acting as an employee (staff pharmacist) of ReCept Pharmacy #1, 800 8th Ave., Suite 130, Fort Worth, Texas 76104, dispensed triamterene/ hydrochlorothiazide 37.5 mg - 25 mg tablets to patient J.B. on a refill of a prescription calling for Ultracet (tramadol/ acetaminophen 37.5 mg - 325 mg tablets). The prescription bottle was labeled "tramadol/ace 37.5/325 mg tab." The patient took the incorrect medication and experienced adverse effects, including having leg cramps and diarrhea. The prescription was assigned prescription number 173292.

By letter dated July 2, 2010, ReCept Pharmacy #1 was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or administrative hearing. By his signature on this Order, Nicky Lee Otts, Corporate President of ReCept Pharmacy LP, for and on behalf of ReCept Pharmacy #1 neither admits nor denies the truth of the matters previously set out in this Order, agrees that the Texas State Board of Pharmacy has jurisdiction in this matter and waives the pharmacy's right to informal conference, to notice of hearing, to a formal administrative hearing, and to judicial review of this Order.

Nicky Lee Otts understands that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board's consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

Nicky Lee Otts, on behalf of ReCept Pharmacy #1, agrees to the entry of an Order disposing of the need for further disciplinary action in this matter and agrees to comply with the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacy license number 23060 held by ReCept Pharmacy #1 (hereinafter referred to as "Respondent") shall be, and such license is hereby reprimanded.

It is further ORDERED that Respondent shall develop and implement policies and procedures for a Continuous Quality Improvement Program for purposes of preventing and handling dispensing errors. The Continuous Quality Improvement Program shall include pharmacist peer review in compliance with guidelines approved by the Texas State Board of Pharmacy. In addition, the policies and procedures for pharmacist peer review shall state that:

(1) The peer review committee will:
- review incident reports;
- determine what caused errors;
- make recommendations to correct the problem that caused the errors; and
- monitor the changes to determine if the changes have improved the operation of Respondent and reduced errors.

(2) The peer review committee must be comprised of at least two employees of Respondent, including the pharmacist-in-charge and other pharmacist(s) or personnel who are employees of Respondent. The committee shall not be solely comprised of a district or regional manager/supervisor and the pharmacist-in-charge and shall not be used for personnel evaluation purposes.

(3) The peer review committee will meet regularly, and no less than quarterly.

(4) The peer review committee will make a record indicating:
- date of meeting
- location of meeting;
- names of persons attending the meeting;
- description of activities;
- discussion of problems in Respondent's operation (e.g., work flow, dispensing process);
- findings;
- description of recommendations; and
- review of actions or changes relating to individuals, systems, or processes made as a result of previous recommendations.

Respondent shall submit a report and/or documentation of such policies and procedures to the Texas State Board of Pharmacy, Enforcement Division, within ninety (90) days after the entry of this Order. Copies of forms used by Respondent to collect the data on

errors committed at the pharmacy (i.e., incident report forms) must be submitted to the Texas State Board of Pharmacy, as well as any other peer review forms that have been developed by Respondent. Additionally, records of the peer review committee, as described in subparagraph (4) above, shall be maintained for two (2) years at the location of Respondent and made available for inspection by Texas State Board of Pharmacy employees.

It is further ORDERED that Respondent shall allow the staff of the Texas State Board of Pharmacy, Enforcement Division, to directly contact Respondent on any matter regarding the enforcement of this Order.

It is finally ORDERED that failure to comply with any of the terms and conditions in this Order constitutes a violation and shall be grounds for further disciplinary action against the Texas pharmacy license held by Respondent.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND DATED THIS 11th day of August, 2010.

W. Benjamin Fay, R.Ph.
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

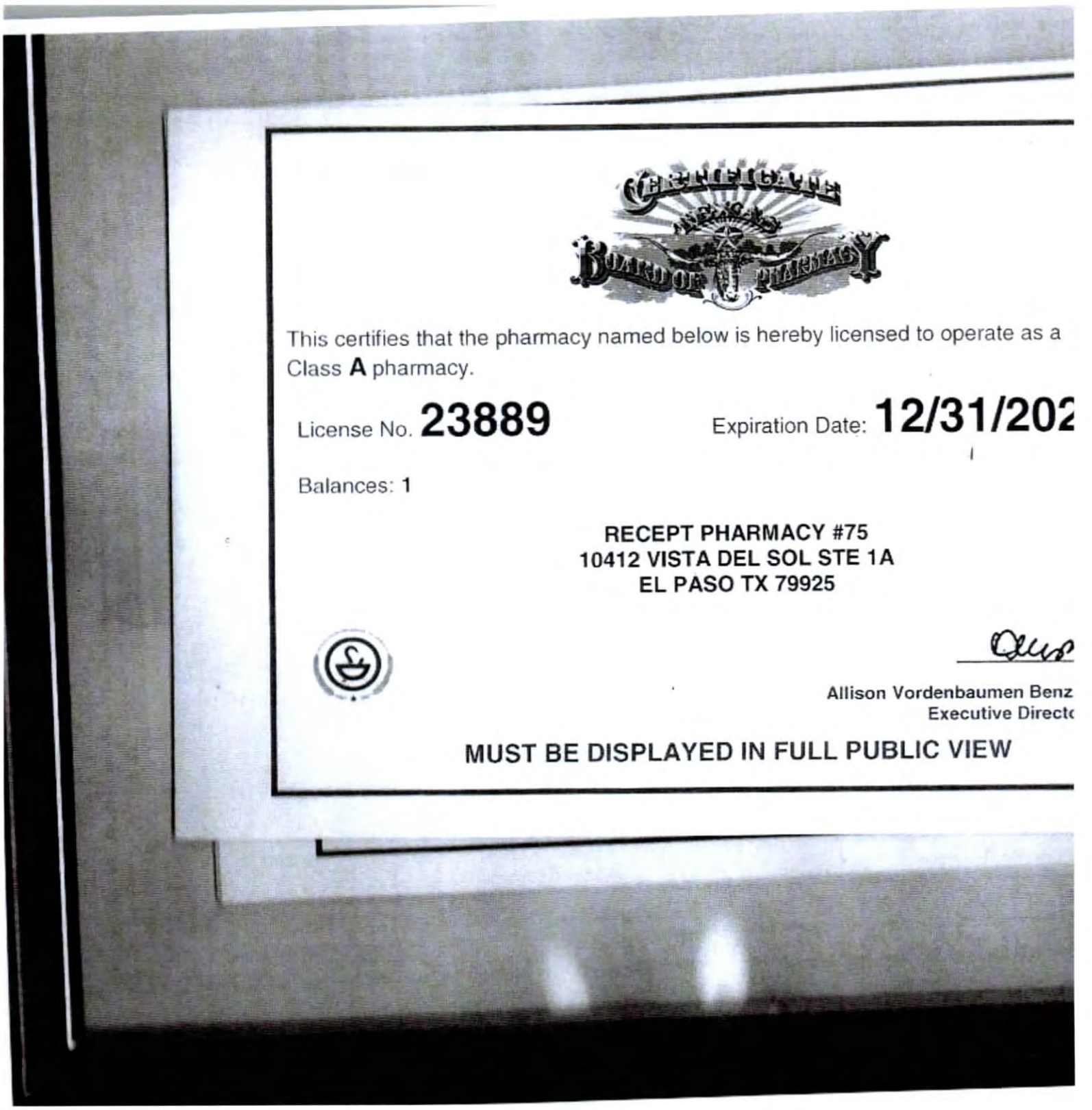
Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Nicky Lee Otts, R.Ph., Corporate President of ReCept Pharmacy LP,
for and on behalf of ReCept Pharmacy #1

APPROVED AS TO FORM:

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy



BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **23889**

Expiration Date: **12/31/202**

Balances: 1

RECEPT PHARMACY #75
10412 VISTA DEL SOL STE 1A
EL PASO TX 79925

Allison Vordenbaumen Benz
Executive Directo

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Re:	Recept Pharmacy #75
Address:	10412 Vista Del Sol, Suite 1A El Paso, Texas 79925
License No.:	23889
Date Issued:	December 14, 2004
Licensure Status:	Active
Expiration Date:	December 31, 2022
Type of Pharmacy:	Community – Class A
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Recept Pharmacy #75(Texas Pharmacy License #23889) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Megan G. Holloway

Megan G. Holloway
Deputy General Counsel
Texas State Board of Pharmacy

June 8, 2021
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

TEXAS STATE BOARD OF PHARMACY

June 8, 2021

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

RE: ReCept Pharmacy #75 (Texas Pharmacy License #23889)

Hello:

On June 1, 2021, the Texas State Board of Pharmacy (TSBP) received a request for information regarding the above-named licensee.

We have enclosed documents responsive to the request.

The Texas State Board of Pharmacy would like to request your assistance in assessing the customer service you received. We appreciate your time and input. Please use https://www.surveymonkey.com/r/WYGCJKS to access the survey.

If you need additional information, please contact Margarita Zamarripa, Senior Administrative Assistant, at (512) 305-8028.

Sincerely,

Open Records
Texas State Board of Pharmacy

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

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Limited Partnership for ReCept Pharmacy, L.P. (file number 800282045), a Domestic Limited Partnership (LP), was filed in this office on December 18, 2003.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on April 06, 2021.

Ruth R. Hughs
Secretary of State

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy or* X ***Ownership Change*** *(Provide current license number if making changes:* **PH** 02866 _

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Truax Patient Services, LLC

Physical Address: 1112 Railroad Street SE, #4, Bemidji, MN 56601

Mailing Address: 1112 Railroad Street SE, #4, Bemidji, MN 56601

City: Bemidji State: MN Zip Code: 56601

Telephone: 218-444-8217 Fax: 218-444-2267

✓ Toll Free Number: 844-289-3981 (Required per NAC 639.708)

E-mail: bwtruax@gmail.com Website: www.tps-rx.com

Managing Pharmacist: Brian W. Truax License Number: 114768 (MN)

TYPE OF PHARMACY AND	**SERVICES PROVIDED**
Yes/No	Yes/No
☐ ☒ Retail	☐ ☒ Off-site Cognitive Services
☐ ☒ Hospital (# beds____)	☐ ☒ Parenteral **
☐ ☒ Internet	☐ ☒ Parenteral (outpatient)
☐ ☒ Nuclear	☐ ☒ Outpatient/Discharge
☐ ☒ Ambulatory Surgery Center	☒ ☐ Mail Service
☐ ☒ Community	☐ ☒ Long Term Care
☒ ☐ Other: Mail order	☐ ☒ Sterile Compounding **
	☐ ☒ Non Sterile Compounding
All boxes must be checked	☐ ☒ Mail Service Sterile Compounding **
For the application to be complete	☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☒ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tyler Truax
Print Name of Authorized Person

10/29/20
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Minnesota

Parent Company if any: Truax Patient Services, LLC

Mailing Address: 1112 Railroad Street SE, Suite #4

City: Bemidji State: MN Zip: 56601

Telephone: 218-444-8217 Fax: 218-444-2267

Contact Person: Brian W. Truax

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Brian W. Truax [redacted]sland View Drive NE, Bemidji, MN 56601
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information
There is no stock register because it is a limited liability company. Please see operating agreement attached.

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 6 pm Saturday 9 am 12 pm

Sunday Closed am _____ pm 24 Hours On call services

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Brian W. Truax

Responsible Person of Truax Patient Services, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Brian Truax

Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian W. Truax

Print Name of Authorized Person

10/29/20

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Minnesota)
) ss.
Beltrami COUNTY)

I, Brian W. Truax, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Member-Manager for Truax Patient Services, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Brian W. Truax, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Brian Truax
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
29 day of October, 2020.

NOTARY PUBLIC

JENNIFER ELIZABETH HAZELTON
NOTARY PUBLIC - MINNESOTA
My Comm. Exp. Jan. 31, 2023

State of Minnesota

BOARD OF PHARMACY
2829 UNIVERSITY AVE SE #530
MINNEAPOLIS, MN 55414-3251

HAS ISSUED

PHARMACY LICENSE NUMBER: 263862 (ACTIVE)
Limited Service

To: TRUAX PATIENT SERVICES
1112 RAILROAD ST SE, STE 4
BEMIDJI MN 56601

EFFECTIVE DATE
05/04/2020

EXPIRATION DATE
06/30/2021

State of Minnesota

BOARD OF PHARMACY
2829 UNIVERSITY AVE SE #530
MINNEAPOLIS, MN 55414-3251

HAS ISSUED

PHARMACY LICENSE
NUMBER: 263862 (ACTIVE)
Check with MN Board of Pharmacy

To: TRUAX PATIENT SERVICES

EFFECTIVE DATE
05/04/2020

EXPIRATION DATE
06/30/2021

EXHIBIT A
Members

Name & Address	Units	Percentage Interest	Capital Commitment
Brian Truax	100 Units	100%	$100,000.00
TOTAL:	**100 Units**	**100%**	$100,000.00

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF REGISTRATION
FOREIGN LIMITED-LIABILITY COMPANY

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Truax Patient Services, LLC** did on 08/27/2020 file in this office its registration to do business in this state and is now on file and of record in the office of the Nevada Secretary of State, and further, that said entity is at the date of this certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/27/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202008271035020
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Truax Patient Services, LLC

Nevada Business Identification # NV20201878353
Expiration Date: 08/31/2021

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/27/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202008271035021
You may verify this certificate online at http://www.nvsos.gov

PH # (218) 444-8217
FAX # (218) 444-2267

TRUAX PATIENT SERVICES

NATIONAL SPECIALTY/MAIL ORDER PHARMACY

1112 RAILROAD ST SE STE#4, BEMIDJI, MN 56601

RE: Letter of explanation describing State of Maine BOP Reprimand.

Dear State Board of Pharmacy,

Truax Patient Services (TPS) failed to apply for a license within 7 days prior to change of location for the Maine BOP out of state license. I (Brian Truax PIC) did not realize TPS's noncompliance. It is my job to make sure of compliance and I missed it. TPS continued to mail prescriptions to the state of Maine without proper licensure. TPS agreed to reprimand and paid fine. The Maine BOP approved the TPS change of location/new out of state licensure application and TPS is currently licensed in the state of Maine.

Thank you for your consideration,

Brian Truax RPh/PIC

CASHIER'S CHECK

SERIAL #: 0938101822

ACCOUNT#: 4861-511830

0009381	11-24
Office AU #	1210(8)

Remitter: BRIAN TRUAX
Purchaser: BRIAN TRUAX
Purchaser Account: 6681174832
Operator I.D.: u585868 main1508
Funding Source: Paper Items(s)

August 10, 2018

PAY TO THE ORDER OF ***TREASURER, STATE OF MAINE***

Eleven thousand seven hundred fifty dollars and no cents

$11,750.00

Payee Address:
Memo:

VOID IF OVER US $ 11,750.00

NON-NEGOTIABLE

WELLS FARGO BANK, N.A.
2024 PAUL BUNYAN DR NW
BEMIDJI, MN 56601
FOR INQUIRIES CALL (480) 394-3122

NOTICE TO PURCHASER -- IF THIS INSTRUMENT IS LOST, STOLEN OR DESTROYED, YOU MAY REQUEST CANCELLATION AND REISSUANCE. AS A CONDITION TO CANCELLATION AND REISSUANCE, WELLS FARGO BANK MAY IMPOSE A FEE AND REQUIRE AN INDEMNITY AGREEMENT AND BOND.

Purchaser Copy

FB004 M4203 50211976

Paul R. LePage
Governor

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

August 10, 2018

Via email: bwtruax@tps-rx.com

Brian Truax
Dba Truax Patient Services
1112 Railroad Street SE Suite #4
Bemidji MN 56601

Re: NOTICE OF PRELIMINARY DENIAL (MO 40002380) 2018-PHA-14737

Dear Mr. Truax:

At its meeting on June 7, 2018, the Maine Board of Pharmacy ("the Board") reviewed your initial application for mail order pharmacy license, which was submitted on March 12, 2018. The Board voted to preliminarily deny this application based upon your apparent violation of 32 M.R.S. § 13751 (1) by failing to obtain an active license prior to shipping prescription drugs to Maine. You have reported making twenty (20) shipments to Maine during the period of January 15, 2018, to April 18, 2018. Pursuant to 10 MRS § 8003 (5-A)(A)(1) misrepresentation in obtaining a license specifically a misrepresentation was made in an amended application page you provided on March 20, 2018 indicating the change of location occurred on March 2, 2018.

In lieu of denying your pending application outright, the Board voted to offer you a consent agreement as a means to resolve this issue without an adjudicatory hearing. A consent agreement is a voluntary, negotiated agreement among you, the Board and the Office of the Attorney General. The terms of the consent agreement are spelled out in the enclosed Consent Agreement.

If you do not want to sign the Consent Agreement, by law, you have the right to request a hearing to contest the Board's preliminary denial of your application for licensure. If you wish to request a hearing regarding the preliminary denial of your application, you must do so **within thirty (30) days of receipt of this letter** by submitting a written request to the Maine Board of Pharmacy, Department of Professional and Financial Regulation, 35 State House Station, Augusta, ME 04333. **If you fail to submit a timely written request for hearing to the Board and fail to sign**

Signed ; Sent 8/10/18

STATE OF MAINE
BOARD OF PHARMACY

IN RE:)
)
Brian Truax)
dba Truax Patient Services) CONSENT AGREEMENT
)
Complaint No. 2018-PHA-14737)

FedEX said it will be there Monday 8/13/18

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Brian Truax dba Truax Patient Services in the State of Maine. The parties to this Consent Agreement are: Brian Truax dba Truax Patient Services ("Truax"), the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. From July 17, 2012, until January 13, 2018, Truax operated a mail order pharmacy at the registered location of 602 Beltrami Avenue NW, Suite 105 in Bemidji, Minnesota, which was licensed in Maine as a mail order pharmacy, license number MO40001335.
2. On January 13, 2018, Truax relocated its mail order pharmacy to 1112 Railroad Street SE Suite #4, in Bemidji, Minnesota.
3. Pursuant to Board Rules Chapter 11 § 3, upon change of location of a mail order pharmacy, the mail order pharmacy must file a new application with the Board no less than 7 days prior to the change.

the preliminary denial of Truax's application for the change of location of its mail order pharmacy license will become final.

COVENANTS

10. Truax admits to the facts as stated above and admits that such conduct constitutes grounds for discipline as follows:

    a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(4) for violating a governing law of the Board, specifically 32 M.R.S. § 13751(1) by repeatedly making shipments of pharmaceutical drugs into Maine from a location that was not properly licensed by the Board as a mail order pharmacy;

    b. Pursuant to 10 MRS § 8003 (5-A)(A)(1) for making a misrepresentation in an obtaining a license, specifically by modifying the change-of-location date in the application to March 2, 2018;

    c. Pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a Board rule, specifically Board Rules Chapter 11 § 3, by failing to file a new mail order pharmacy application with the Board no less than 7 days prior to a change of location.

11. As DISCIPLINE for the violations admitted to in paragraph 12 above, Truax agrees to accept the following discipline and conditions:

    a. A REPRIMAND;

    b. A condition to cease desist from shipping pharmaceutical drugs to patients in Maine until validly licensed by the Board; and

    c. The imposition of a CIVIL PENALTY in the amount of eleven thousand seven hundred and fifty dollars ($11,750.00); which consists of $500.00 per prescription

unless Truax fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Truax and this Consent Agreement will be admitted into evidence at any future adjudicatory hearings involving Truax. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against Truax.

19. Truax acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: _____

_____
BRIAN TRUAX
d/b/a TRUAX PATIENT SERVICES

DATED: _____

_____
JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: _____

_____
ANDREW L. BLACK
Assistant Attorney General

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL & OCCUPATIONAL REGULATION
COMPLAINT DIVISION
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Paul R. LePage
Governor

Anne L. Head
Commissioner

August 28, 2018

Brian Truax
d/b/a Truax Patient Services
1112 Railroad St. SE, Suite #4
Bemidji, MN 56601-4871

Re: Complaint No. 2018-PHA-14737

Dear Mr. Truax:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy ("Board") and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $11,750.00. Your fine is paid in full and this complaint file is now closed; however, you are cautioned that in accordance with paragraph 11 (b) of the Consent Agreement you are under an obligation to cease and desist from shipping pharmaceutical drugs to patients in Maine until validly licensed by the Board.

Please feel free to contact our office at (207) 624-8696 with any questions.

Sincerely,

Complaint Division

Enclosure

cc: Andrew Black, Esq., Assistant Attorney General
Geraldine Betts, Board Administrator
Thomas Avery, Chief Field Investigator
Jessica Gowell, Professional Licensing Supervisor
Meagan Damon, Senior Consumer Assistant Specialist
Kelly McLaughlin, Comprehensive Health Planner / Complainant

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
Brian Truax	)	CONSENT AGREEMENT
dba Truax Patient Services	)	
	)	
Complaint No. 2018-PHA-14737	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Brian Truax dba Truax Patient Services in the State of Maine. The parties to this Consent Agreement are: Brian Truax dba Truax Patient Services ("Truax"), the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. From July 17, 2012, until January 13, 2018, Truax operated a mail order pharmacy at the registered location of 602 Beltrami Avenue NW, Suite 105 in Bemidji, Minnesota, which was licensed in Maine as a mail order pharmacy, license number MO40001335.
2. On January 13, 2018, Truax relocated its mail order pharmacy to 1112 Railroad Street SE Suite #4, in Bemidji, Minnesota.
3. Pursuant to Board Rules Chapter 11 § 3, upon change of location of a mail order pharmacy, the mail order pharmacy must file a new application with the Board no less than 7 days prior to the change.

BT 8/10/18

the preliminary denial of Truax's application for the change of location of its mail order pharmacy license will become final.

COVENANTS

10. Truax admits to the facts as stated above and admits that such conduct constitutes grounds for discipline as follows:

    a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(4) for violating a governing law of the Board, specifically 32 M.R.S. § 13751(1) by repeatedly making shipments of pharmaceutical drugs into Maine from a location that was not properly licensed by the Board as a mail order pharmacy;

    b. Pursuant to 10 MRS § 8003 (5-A)(A)(1) for making a misrepresentation in an obtaining a license, specifically by modifying the change-of-location date in the application to March 2, 2018;

    c. Pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a Board rule, specifically Board Rules Chapter 11 § 3, by failing to file a new mail order pharmacy application with the Board no less than 7 days prior to a change of location.

11. As DISCIPLINE for the violations admitted to in paragraph 12 above, Truax agrees to accept the following discipline and conditions:

    a. A REPRIMAND;

    b. A condition to cease desist from shipping pharmaceutical drugs to patients in Maine until validly licensed by the Board; and

    c. The imposition of a CIVIL PENALTY in the amount of eleven thousand seven hundred and fifty dollars ($11,750.00); which consists of $500.00 per prescription

BT 8/10/18

unless Truax fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Truax and this Consent Agreement will be admitted into evidence at any future adjudicatory hearings involving Truax. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against Truax.

19. Truax acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 8/10/18

BRIAN TRUAX
d/b/a TRUAX PATIENT SERVICES

DATED: 8/19/2018

JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 8/23/2018

ANDREW L. BLACK
Assistant Attorney General

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000139009192
Process Date: 09/24/2018
Page: 1 of 2

TRUAX PATIENT SERVICES

SENSITIVE INFORMATION ENCLOSED

To: CEO or President
TRUAX PATIENT SERVICES
1112 RAILROAD ST SE STE 4

BEMIDJI, MN 56601-4871

From: The National Practitioner Data Bank
Re: Notification of a Report in the Data Bank

Notice of an Action Reported to the NPDB

Dear Health Care Organization, Provider or Supplier:

This notice is to inform you that your organization is the subject of a report submitted to the National Practitioner Data Bank (NPDB). The report was submitted by an organization registered with the NPDB in accordance with federal regulations. The NPDB must notify the subject of such reports so they may review the full report and check its accuracy. This letter serves as your notification.

What is the NPDB?

The NPDB is a federal information repository for reports related to medical malpractice payments and adverse health care actions. The NPDB was created by Congress and is operated by the Health Resources and Services Administration (HRSA). Reports are maintained exactly as submitted by the reporting organization, and are maintained permanently.

For a visual guide to the NPDB, visit https://www.npdb.hrsa.gov/guide.

How to view the complete report

You may access the report online at any time. Enter the web address in your internet browser window. Enter the report number and password to sign in. **Type the password exactly as it is shown in this letter. Please note: This password expires on October 24, 2018.** You must change the password when you sign in for the first time. For security purposes, you must also provide additional personal information when you sign in.

Web Address: https://www.npdb.hrsa.gov/report

Report Number: 5500 0001 3900 9192

Password: [redacted]

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000139009192
Process Date: 09/24/2018
Page: 1 of 3
TRUAX PATIENT SERVICES
For authorized use by:
TRUAX PATIENT SERVICES

TRUAX PATIENT SERVICES

OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION

STATE LICENSURE ACTION **Date of Action:** 08/23/2018

Initial Action	Basis for Initial Action
- REPRIMAND OR CENSURE	- FAILURE TO MEET LICENSING BOARD REPORTING REQUIREMENTS - OTHER, SEE SECTION C. OF THE REPORT FOR DETAILS

A. REPORTING ENTITY

Entity Name:	OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
Address:	35 STATE HOUSE STA
City, State, Zip:	AUGUSTA, ME 04333-0035
Country:	
Name or Office:	KARISSSA DAVAN
Title or Department:	ATTORNEY
Telephone:	(207) 624-8615
Entity Internal Report Reference:	2018-PHA-14737
Type of Report:	INITIAL

B. SUBJECT IDENTIFICATION INFORMATION (ORGANIZATION)

Organization Name:	TRUAX PATIENT SERVICES
Other Organization Name(s) Used:	
Business Address:	1112 RAILROAD ST SE STE 4
City, State, ZIP:	BEMIDJI, MN 56601-4871
Organization Type:	PHARMACY (345)
Names and Titles of Principal Officers and Owners (POO):	TRUAX, BRIAN
Federal Employer Identification Numbers (FEIN):	455480896
Social Security Numbers (SSN):	
Individual Taxpayer Identification Numbers (ITIN):	
State License Number, State of Licensure:	MO40001335, ME
Is the Subject a health care entity that provides health care services and engages in a formal peer review process for the purpose of furthering quality health care?:	NO
Drug Enforcement Administration (DEA) Numbers:	
Clinical Laboratory Act (CLIA) Numbers:	
Food and Drug Administration (FDA) Numbers:	
National Provider Identifiers (NPI):	
Medicare Provider/Supplier Numbers:	
Name(s) of Health Care Entity (Entities) With Which Subject Is Affiliated or Associated (Inclusion Does Not Imply Complicity in the Reported Action.):	
Business Address of Affiliate:	
City, State, ZIP:	
Nature of Relationship(s):	

NATIONAL PRACTITIONER DATA BANK

NPDB

P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000139009192
Process Date: 09/24/2018
Page: 2 of 3
TRUAX PATIENT SERVICES
For authorized use by:
TRUAX PATIENT SERVICES

C. INFORMATION REPORTED

Type of Adverse Action:	STATE LICENSURE
Basis for Action:	FAILURE TO MEET LICENSING BOARD REPORTING REQUIREMENTS (A3)
	OTHER - NOT CLASSIFIED, SPECIFY (99)
Other, as Specified:	MISREPRESENTATION TO OBTAIN A LICENSE
	OTHER - NOT CLASSIFIED, SPECIFY (99)
Other, as Specified:	FAILURE TO APPLY FOR A LICENSE WITHIN 7 DAYS PRIOR TO CHANGE OF LOCATION
Name of Agency or Program That Took the Adverse Action Specified in This Report:	MAINE BOARD OF PHARMACY
Adverse Action Classification Code(s):	REPRIMAND OR CENSURE (3138)
Date Action Was Taken:	08/23/2018
Date Action Became Effective:	08/23/2018
Length of Action:	INDEFINITE
Total Amount of Monetary Penalty, Assessment and/or Restitution:	
Is Subject Automatically Reinstated After Adverse Action Period Is Completed?:	NO
Description of Subject's Act(s) or Omission(s) or Other Reasons for Action(s) Taken and Description of Action(s) Taken by Reporting Entity:	The mail order pharmacy changed location on 1/13/2018 and did not file an application 7 days prior as required by Maine Board of Pharmacy rules. A misrepresentation was made as to the time of the move and during the time after the move, product continued to be shipped to Maine.

☐ Subject identified in Section B has appealed the reported adverse action.

D. SUBJECT STATEMENT

If the subject identified in Section B of this report has submitted a statement, it appears in this section.

E. REPORT STATUS

Unless a box below is checked, the subject of this report identified in Section B has not contested this report.

☐ This report has been disputed by the subject identified in Section B.

☐ At the request of the subject identified in Section B, this report is being reviewed by the Secretary of the U.S. Department of Health and Human Services to determine its accuracy and/or whether it complies with reporting requirements. No decision has been reached.

☐ At the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services and a decision was reached. The subject has requested that the Secretary reconsider the original decision.

☐ At the request of the subject identified in Section B, this report was reviewed by the Secretary of the U.S. Department of Health and Human Services. The Secretary's decision is shown below:

NATIONAL PRACTITIONER DATA BANK
NPDB
P.O. Box 10832
Chantilly, VA 20153-0832

https://www.npdb.hrsa.gov

DCN: 5500000139009192
Process Date: 09/24/2018
Page: 3 of 3
TRUAX PATIENT SERVICES
For authorized use by:
TRUAX PATIENT SERVICES

Date of Original Submission: 09/24/2018
Date of Most Recent Change: 09/24/2018

This report is maintained under the provisions of: Section 1921

The information contained in this report is maintained by the National Practitioner Data Bank for restricted use under the provisions of Section 1921 of the Social Security Act, and 45 CFR Part 60. All information is confidential and may be used only for the purpose for which it was disclosed. Disclosure or use of confidential information for other purposes is a violation of federal law. For additional information or clarification, contact the reporting entity identified in Section A.

END OF REPORT

Truax Patient Services
License No. PH 02866

Operating Agreement

OPERATING AGREEMENT

FOR

TRUAX PATIENT SERVICES, LLC

Dated: September 1, 2020

THE INTERESTS IN THIS COMPANY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR UNDER THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER THAT ACT AND THE APPLICABLE STATE SECURITIES LAWS, OR THE COMPANY WILL HAVE RECEIVED AN OPINION OF COUNSEL (WHICH COUNSEL AND OPINION WILL BE SATISFACTORY TO THE COMPANY'S COUNSEL) THAT REGISTRATION OF SUCH SECURITIES UNDER THAT ACT AND UNDER THE APPLICABLE STATE SECURITIES LAWS IS NOT REQUIRED.

THE INTERESTS IN THIS COMPANY ARE SUBJECT TO THE RESTRICTIONS AND PROVISIONS OF THIS AGREEMENT AND MAY ONLY BE DISPOSED OF OR ENCUMBERED IN COMPLIANCE HEREWITH.

THIS **OPERATING AGREEMENT** (this "Agreement") is made and entered into as of this 1st day of September, 2020, by and among **TRUAX PATIENT SERVICES, LLC**, a Minnesota Limited Liability Company (the "Company"), and all of its Members (as defined below).

RECITALS

WHEREAS, the parties have agreed to organize and operate a Limited Liability Company in accordance with the provisions of the Act (as defined below); and

WHEREAS, the parties desire to enter into this Agreement to formally define and express all of the terms and conditions of the Company and their respective rights and obligations with respect thereto.

NOW, THEREFORE, in consideration of the premises, the mutual covenants herein contained, and other good and valuable consideration, the parties, intending to be legally bound, hereby agree as follows:

ARTICLE I
Defined Terms

Capitalized words and phrases used and not otherwise defined elsewhere in this Agreement will have the following meanings:

1.1 "Act" means the Minnesota Revised Uniform Limited Liability Company Act, and any successor statute, as amended from time-to-time.

1.2 "Adjusted Capital Account Deficit" means, with respect to any Member, the deficit balance, if any, in the Member's Capital Account as of the end of the applicable taxable year, after giving effect to the following adjustments:

(i) The deficit shall be decreased by the amounts which the Member is obligated to restore under Section 4.5.2, or is deemed obligated to restore under Section 1.704-2(g)(2) and (i)(5) of the Regulations; and

(ii) The deficit shall be increased by the items described in Section 1.704-1(b)(2)(ii)(d)(4), (5), and (6) of the Regulations.

1.3 "Adjusted Capital Contributions" means, as of any day, a Member's total Capital Contributions *less* all amounts actually distributed to the Member under Article IV and Article VII of this Agreement. The amount of the Adjusted Capital Contribution shall be increased by the amount of Company liabilities assumed by the Member in connection with the distribution or are secured by any Company property distributed to the Member. If any Interest is transferred in accordance with the terms of this Agreement, then the transferee succeeds to the Adjusted Capital Contributions of the transferor to the extent the Adjusted Capital Contributions relate to the Interest transferred.

1.4 "Affiliated Individual" means an individual who (i) directly or indirectly through another entity has an ownership interest in the Company, or (ii) is a grantor, trustee or beneficiary of any trust that directly or indirectly through another entity has an ownership interest in the Company. Only the undersigned Affiliated Individual may exercise the Membership Rights (as defined below) unless otherwise approved by the Manager in writing. Each Affiliated Individual of a Member shall be bound by the terms and conditions of this Agreement, and hereby assume all rights, duties, liabilities and obligations such Member under this Agreement. No Affiliated Individual of a Member may transfer any ownership interest in such Member without the prior written consent of the Manager.

1.5 "Agreement" means this Operating Agreement, as amended, modified, supplemented or restated from time-to-time in accordance herewith.

1.6 "Applicable Law" means all applicable federal, state and local law, including, without limitation, all applicable statutes, codes, regulations, ordinances and rules, and all applicable case law, administrative decisions, and agency requirements applicable to the Members and the Company.

1.7 "Available Commitment" means, as of any date of determination, the excess of a Member's Capital Commitment over the aggregate amount of such Member's Capital Contributions, as such amount may be adjusted from time to time in accordance with this Agreement.

1.8 "Bankrupt Member" means as to any Member or Affiliated Individual of a Member: (i) the Member's or Affiliated Individual's filing of a voluntary petition in bankruptcy; (ii) the filing of an involuntary petition in bankruptcy against the Member or Affiliated Individual if such petition is not dismissed within one hundred twenty (120) days of the date of filing; (iii) the Member's or Affiliated Individual's making of a general assignment for the benefit of creditors; (iv) the Member's or Affiliated Individual's seeking, consenting or acquiescing in the appointment of a trustee, receiver or liquidator for all or a substantial part of the Member's or Affiliated Individual's property; (v) the appointment of such a trustee, receiver or liquidator for the Member or Affiliated Individual which appointment is not vacated or stayed within one hundred twenty (120) days; (vi) the sequestration by a court of competent jurisdiction of substantially all of the Member's or Affiliated Individual's assets; (vii) the adjudication of the Member or Affiliated Individual as a bankrupt or insolvent, or entry against the Member or Affiliated Individual of an order for relief, in any bankruptcy or insolvency proceeding; or (viii) the filing by the Member or Affiliated Individual of a petition or answer seeking for the Member or Affiliated Individual any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any statute, law or regulation, or filing of an answer or other pleading admitting or failing to contest the material allegations of a petition filed against the Member or Affiliated Individual in any proceeding of this nature.

1.9 "Capital Account" means the account to be maintained by Company for each Member in accordance with the following provisions:

(i) A Member's Capital Account is credited with the Member's Capital Contributions, the amount of any Company liabilities assumed by the Member (or which are secured by Company property distributed to the Member), the Member's allocable share of Profits and any item of income or gain specially allocated to the Member under the provisions of Article IV; and

(ii) A Member's Capital Account is debited with the amount of money and the fair market value of any Company property distributed to the Member, the amount of any liabilities of the Member assumed by the Company (or which are secured by property contributed by the Member to the Company), the Member's allocable share of Losses and any item of expense or loss specially allocated to the Member under the provisions of Article IV.

If any Interest is transferred under this Agreement, then the transferee shall succeed to the Capital Account of the transferor to the extent the Capital Account is attributable to the transferred Interest. It is intended that the Capital Accounts of all Members be maintained in compliance with the provisions of Section 1.704-1(b) of the Regulations, and all provisions of this Agreement relating to the maintenance of Capital Accounts are to be interpreted and applied in a manner consistent with that Regulation.

1.10 "Capital Commitment" means, with respect to a Member, the total the total amount of cash and the fair market value of any other property or services contributed, or to be contributed, (or deemed contributed under Section 1.704-1(b)(2)(iv)(d) of the Regulations) to the Company by a Member, net of liabilities assumed or to which the property is subject, as set forth opposite such Member's name on **Exhibit A**.

1.11 "Capital Contribution" means a contribution of capital made by a Member pursuant to Article III.

1.12 "Capital Proceeds" means the gross receipts received by the Company from a Capital Transaction.

1.13 "Capital Transaction" means any transaction, not in the ordinary course of business, which results in the Company's receipt of cash or other consideration other than Capital Contributions, including, but not limited to, proceeds of sales or exchanges or other dispositions of property not in the ordinary course of business, financings, re-financings, condemnations, and insurance proceeds for the destruction of assets used in the trade or business of the Company.

1.14 "Cash Flow" means all cash funds derived from operations of the Company (including interest received on Reserves), *less* cash funds used to pay current operating expenses and to pay or establish reasonable Reserves for future expenses, debt payments, capital improvements, contingencies, and replacements as determined by the Manager from time-to-time. Cash Flow does not include Capital Proceeds, but is increased by the reduction of any Reserve previously established. Cash Flow is not reduced by non-cash charges, including, but not limited to, depreciation, and amortization.

1.15 "Certificate of Organization" means certificate of organization of the Company filed under the Act with the Secretary of State, as may be amended or restated from time-to-time.

1.16 "Code" means the Internal Revenue Code of 1986, as amended, or any corresponding provision of any succeeding law.

1.17 "Confidential Information" means any and all confidential and proprietary information of the Company (whether transmitted by oral, written, electronic or any other means), including, without limitation, business plans, trade secrets, intellectual property, patents, trademarks, copyrights, know-how, data, inventions, models and strategies, developments, concepts, processes, technical or engineering developments, marketing plans, marketing materials, negotiation strategies, compensation structure, pension and profit sharing plans, contracts, leases, agreements, financial statements, balance sheets, tax records, accounting procedures, assets and liabilities, claims, settlements, pending litigation of any nature, personnel history, and any other information concerning the business or affairs of the Company. Confidential Information shall include information that is based upon or derived from Confidential Information. Confidential Information does not include information which is or becomes available or known to the public other than as a result of a disclosure by the respective Member or by the Member's representatives in violation of this Agreement.

1.18 "Decedent" shall refer to a Member or Affiliated Individual who has died.

1.19 "Fair Market Value of the Company" means the fair market value of the Company as determined by the Valuator.

1.20 "Interest" means the ownership interest and rights of a Member, including, without limitation, the Member's right to share of the Profits and Losses of, and the right to receive distributions from, the Company, and the right to consent or approve matters as set forth in this Agreement. The Interest may be expressed as a percentage representing the ratio of the number of Units held by a Member to the total number of issued and outstanding Units.

1.21 "Manager" means Brian Truax.

1.22 "Member" means each Person listed in **Exhibit A** of this Agreement and any Person who subsequently is admitted as a Member of the Company, but shall not include any Person who has ceased to be a Member of Company.

1.23 "Member Minimum Gain" means an amount, with respect to each Member Nonrecourse Liability, equal to the Minimum Gain that would result if such Member Nonrecourse Liability were treated as a Nonrecourse Liability, determined in accordance with the provisions of Section 1.704-2(i)(3) of the Regulations.

1.24 "Member Nonrecourse Deduction" means, for any fiscal year, the net increase during the year in Member Minimum Gain attributable to the Member Nonrecourse Liability reduced, but not below zero, by proceeds of the liability (i) distributed during the year to the Member bearing the economic risk of loss for the liability and (ii) that are both attributable to the liability and allocable to an increase in the Member Minimum Gain.

1.25 "Member Nonrecourse Liability" means any Company liability to the extent the liability is nonrecourse (under Code Section 1001), and a Member or person or entity related to a Member (under Section 1.752-4(b) of the Regulations) bears the economic risk of loss, determined in accordance with Section 1.704-2(b)(4) of the Regulations.

1.26 "Minimum Gain" shall have the meaning set forth in Section 1.704-2(b)(2) and 1.704-2(d) of the Regulations. Minimum Gain shall be computed separately for each Member in a manner consistent with the Regulations under Code Section 704(b).

1.27 "Negative Capital Account" means a Capital Account with a balance of less than zero.

1.28 "Net Capital Proceeds" means the net cash proceeds received by the Company from a Capital Transaction, *less* any portion thereof used to establish Reserves for Company expenses, obligations, and contingencies as determined by the Manager from time-to-time. Net Capital Proceeds shall include all principal and interest payments on any debt obligation received by the Company in any Capital Transaction.

1.29 "Nonrecourse Deductions" shall have the meaning set forth in Section 1.704-2(b)(1) of the Regulations. The amount of Nonrecourse Deductions for a taxable year of the Company equals the net increase, if any, in the amount of Minimum Gain during that taxable year, reduced, but not below zero, by the aggregate distributions made during such year of the proceeds of a Nonrecourse Liability that are allocable to an increase in Minimum Gain, determined in accordance with Section 1.704-2(c) of the Regulations.

1.30 "Nonrecourse Liability" means any liability of the Company with respect to which no Member or Person related to a Member has personal liability determined in accordance with Code Section 752 and the Regulations promulgated thereunder.

1.31 "Person" means and includes an individual, a corporation, a company, a limited liability company, a limited partnership, a partnership, a trust, an unincorporated organization, a government or any department or agency thereof, or any entity similar to any of the foregoing.

1.32 "Positive Capital Account" means a Capital Account with a balance greater than zero.

1.33 "Prime Rate" means the annual rate of interest reported from time to time in The Wall Street Journal under the column "Money Rates" (or any successor column) as being the "Prime Rate."

1.34 "Profits" and "Losses" means, for each taxable year of the Company (or other period for which Profits or Losses must be computed), the Company's taxable income or loss determined in accordance with Code Section 703(a), with the following adjustments:

(i) All items of income, gain, loss, deduction, or credit required to be stated separately under Code Section 703(a)(1) are included in computing taxable income or loss; and

(ii) Any tax-exempt income of the Company, not otherwise taken into account in computing Profits or Losses, is included in computing taxable income or loss; and

(iii) Any expenditures of the Company described in Code Section 705(a)(2)(B), or treated as such under Section 1.704-1(b)(2)(iv)(i) of the Regulations, and not otherwise taken into account in computing Profits or Losses, are subtracted from taxable income or loss; and

(iv) Gain or loss resulting from any taxable disposition of Company property is computed by reference to the adjusted book value of the property disposed of, determined in accordance with Section 1.704-1(b)(2)(iv)(d) through (h) of the Regulations, notwithstanding the fact that the adjusted book value differs from the adjusted basis of the property for federal income tax purposes; and

(v) In lieu of the depreciation, amortization, or cost recovery deductions allowable in computing taxable income or loss, there is taken into account the depreciation computed based upon the adjusted book value of the asset; and

(vi) Notwithstanding any other provision of this definition, any items which are specially allocated pursuant to Section 4.5 of this Agreement are not taken into account in computing Profits or Losses.

1.35 "Purchase Price" means the purchase price for a Selling Member's Offered Interest, as determined pursuant to Section 6.2 of this Agreement.

1.36 "Purchaser" or "Purchasers" means the Person or Persons purchasing or redeeming all or a portion of the Offered Interest from a Selling Member.

1.37 "Regulations" means the income tax regulations, including any temporary regulations, from time-to-time promulgated under the Code, as such regulations may be amended from time-to-time.

1.38 "Reserve" or "Reserves" means amounts deemed sufficient by the Manager, as of the date of determination, for working capital and to pay taxes, insurance, debt service, repairs, replacements or renewals, or other costs and expenses, incident to the operation of the Company.

1.39 "Secretary of State" means the Office of the Secretary of State of the State of Minnesota.

1.40 "Selling Member" means a Bankrupt Member, Severed Member, or legal representative of a Decedent, as the case may be.

1.41 "Separation Date" means the date on which a Member became a Selling Member.

1.42 "Severed Member" means a Member who has been terminated for Cause.

1.43 "Supermajority Vote" means the affirmative vote at least two thirds (2/3) of the Units held by the Members entitled to vote.

1.44 "Transfer" means any disposition (including, but not limited to, gifts, sales, assignments, pledges, encumbrances, bequests, and all other inter vivos or testamentary dispositions) whether voluntary, involuntary or whether pursuant to court order or by operation of law.

1.45 "Units" means the units held by all of the Members of the Company representing one hundred (100%) percent of the ownership of the Company. Each Member shall hold the number of Units set forth after the Member's name on **Exhibit A**, as amended from time-to-time. Units shall not be evidenced by certificates, unless the Manager shall determine otherwise.

1.46 "Valuator" means an independent company with experience in the valuation of health care enterprises selected by the Manager, the cost of which shall be paid by the Company.

ARTICLE II
The Company

2.1 **Contract**. This Agreement is a contract between its parties and is enforceable by the Company against any Member who violates its terms. All Members, past, present and future, must sign this Agreement (or a counterpart hereto) as a condition of membership in the Company.

2.2 **Formation**. The parties have formed a limited liability company pursuant to the Act and have caused the Certificate of Organization to be prepared, executed and filed with the Secretary of State in accordance with the Act. The Members hereby ratify the formation of the Company and acknowledge and agree to constitute this Agreement as the Operating Agreement of the Company. In the event of any inconsistency between any provision contained in this Agreement and any non-mandatory provision of the Act, the provision contained in this Agreement will govern.

2.3 **Name of the Company**. The name of the Company shall be "**TRUAX PATIENT SERVICES, LLC**." The Company may do business under that name or such other names as the Manager may select from time-to-time.

2.4 **Purpose**. The Company may engage in any and all lawful business, purpose or activity in which a limited liability company may be engaged under Applicable Law (including, without limitation, the Act).

2.5 **Term**. The Company will continue in existence perpetually until duly terminated in accordance with this Agreement.

2.6 **Registered Office**. The registered office of the Company in the State of Minnesota shall be located at the address set forth in the Certificate of Organization, or such other location within the State of Minnesota as the Manager may select from time-to-time.

2.7 **Registered Agent**. The name of the Company's registered agent in the State of Minnesota shall be the Person set forth in the Certificate of Organization, or such other Person as the Manager may select from time-to-time.

2.8 **Principal Office**. The initial principal office of the Company shall be at 1112 Railroad Street SE, Suite 4, Bemidji, Minnesota 56601, or such other location within the State of Minnesota as the Manager may select from time-to-time.

2.9 **Title to Company Property**. All of the Company's right, title and interest in the property of Company, including any tangible property, intangible property, real property, personal property and other assets acquired by the Company, shall be held in the name of the Company as an entity. Upon the acquisition of any property, the Members shall execute such documents as may be necessary to reflect the Company's ownership interest in such property and shall record the same in such public offices as shall be necessary to reflect such ownership interest by the Company. No Member shall have an ownership interest in any property of the Company in the Member's own name or right and each Member's percentage Interest shall be personal property for all purposes. Each Member waives any and all rights that it may have to maintain any action for partition of the Company's property.

ARTICLE III
Capital Contributions; Capital Accounts

3.1 **Capital Contributions**. Each Member agrees to contribute or pay to the Company, in immediately available funds or other property, in one or more installments, each such Member's Capital Commitment as set forth on **Exhibit A**.

3.2 **Funding Notices**. The Manager may make a capital call from each Member up to each Member's Available Commitment (each a "Capital Call") by delivering a written notice (each a "Funding Notice") to such Member instructing the Member to pay to the Company all or any portion of its Available Commitment not later than a date (the "Funding Date") that is a business day at least fifteen (15) business days after the date of such Funding Notice; provided, however, that each Funding Notice in respect of any Funding Date shall call for the same proportion of all Members' Available Commitment to be paid to the Company no later than such Funding Date. Each Member shall be obligated to make a Capital Contribution only if the Manager shall have sent a Funding Notice, and then only to the extent set forth in such Funding Notice. No Capital Call with respect to any Member shall be in an amount that exceeds such Member's Available Commitment. The obligation of each Member to pay the balance of its Available Commitment shall accrue regardless of whether one or more of the other Members shall fail to pay all or any portion of their respective Capital Commitments.

3.3 **Other Retained or Recalled Distributions**. The Manager may retain distributions payable to any Member and offset such amount against any such Member's obligation for any Capital Contribution due to the Company from such Member, all or a portion of any Capital Call made, though not yet due to the Company from such Member, and all or a portion of any Capital Call reasonably expected to be made within thirty (30) business days to any Member. Each Member's Available Commitment shall be reduced by the amount of any distribution or proceeds retained by the Manager pursuant to this Section.

3.4 **Default**.

3.4.1 The failure by any Member to make, when due or within five (5) business days thereafter, any portion of the Capital Contribution required to be contributed by such Member pursuant to this Agreement or any other payment required to be made by the Member to the Company shall constitute an "Event of Default" by such Member. Upon the occurrence of an Event of Default, such Member may be deemed a "Defaulting Member" and the following provisions of this Section

will apply. The Manager, in its sole discretion, may choose not to designate any Member as a Defaulting Member and may agree to waive or permit the cure of any Event of Default by a Member, subject to such conditions as the Manager and such Member may agree upon.

3.4.2 A Defaulting Member may, in the sole discretion of the Manager, be terminated for Cause.

3.4.3 A Defaulting Member may, in the sole discretion of the Manager, be charged interest on the unpaid balance of any overdue Capital Contributions or other payments, at the Prime Rate from the date such balance was due and payable through the date full payment for such contribution or payment is actually made. No such additional amount or interest shall be treated as a Capital Contribution hereunder or reduce the Available Commitment of such Defaulting Member.

3.4.4 Except as required by the Act, whenever the vote, consent or decision of Members is required or permitted pursuant to this Agreement, a Defaulting Member shall not be entitled to participate in such vote or consent, or to make such decision, and such vote, consent or decision shall be tabulated or made as if such Defaulting Member was not a Member.

3.4.5 The Manager's exercise of any of the foregoing remedies upon an Event of Default does not preclude the Company from seeking injunctive relief, monetary damages or any other legal remedies to which the Company is entitled in connection with an Event of Default.

3.5 **Third Party Financing; Personal Guarantees**. Notwithstanding anything herein to the contrary, if the Manager determines that the Company requires additional capital, the Company may obtain loan(s) from banking facilities or other Persons at a reasonable interest rate. In the event the Company arranges for financing and the party providing such financing requests the personal guarantee of the Members to secure such financing, each Member shall be required to execute such personal guarantees and to meet any and all other requirements required by the party providing the financing. The Company shall use reasonable efforts to limit the guarantee obligations of its Members to limited, several guarantees, rather than unlimited, joint and several guarantees, if reasonably obtainable without material additional cost or burden to the Company. Each Member shall cross indemnify and hold harmless each of the other Members from and against any and all liabilities, claims, causes of action, damages, costs and expenses (including, but not limited to, reasonable attorneys' fees) ("Claim") relating to any amounts at issue that have been personally guaranteed by any Member such that each Member shall be responsible for a portion of the Claim amount equal to the product of: the total Claim amount *multiplied by* a fraction, the numerator of which equals that Member's Capital Commitment, and the denominator of which equals the total Capital Commitment of all Members. The Company shall use reasonable efforts to cause the release of a Selling Member from any and all personal guarantees signed by the Selling Member with respect to Company debt, if reasonably obtainable without material additional cost or burden to the Company.

3.6 **Failure to Make Additional Contributions**. Upon a Member's failure to make any Capital Contribution or submit a personal guarantee, in whole or in part, the Manager shall have the right to terminate such Member for Cause.

3.7 **No Personal Liability**. Except as otherwise provided in this Article III, no Member shall be required to undertake any personal liability for any obligation of the Company.

3.8 **No Interest on Capital Contributions or Capital Accounts**. No Member shall be paid interest in respect of either the Member's Capital Contributions or the Member's Capital Account balance.

3.9 **Return of Capital Contributions**. Except as otherwise provided in this Agreement or as otherwise required by Applicable Law, no Member shall be entitled to the return of any part of the Member's Capital Contribution. No Member shall have any personal liability for the return of the Capital Contribution of any other Member.

3.10 **Form of Distribution**. If a Member is entitled to receive a return of any part of the Member's Capital Contribution, the Member shall not have the right to receive anything but cash, unless otherwise determined by the Manager.

3.11 **Capital Accounts**. A separate Capital Account shall be maintained for each Member, in accordance with Code and the Regulations.

3.12 **Additional Members; Dilution**. If a new Member shall be admitted to the Company in accordance herewith (each an "Additional Member"), the Manager may issue additional Units to the Additional Member, and the percentage Interests of all existing Members will be diluted on a pro-rata basis proportionate to the percentage Interest held by the existing Members immediately prior to the admission of an Additional Member to the Company. All such dilution of the existing Members will be effected without compensation to the Members from whom such percentage Interests are diluted. As a condition to being admitted to the Company, each Additional Member must comply with the requirements described in this Agreement and must execute and deliver to the Company an agreement to be bound by the terms and conditions of this Agreement. Upon the admission of any Additional Member, **Exhibit A** will be amended by the Manager, without any approval or consent of any Member, to reflect the name, address, and percentage Interest of such Additional Member and to adjust, if necessary, the percentage Interests of the other Members to reflect the addition of the Additional Member.

ARTICLE IV
Distributions; Allocations

4.1 **Distributions**. Subject to maintaining the Company in sound financial and cash position, and establishing such Reserves as are determined by the Manager to be reasonably required for the proper operation of the Company, at times approved by the Manager, the Company shall distribute funds of the Company as provided herein.

4.2 **Distribution of Net Capital Proceeds**. Net Capital Proceeds shall be distributed and applied by the Company in accordance with the following order and priority:

4.2.1 To the payment of debts and liabilities of the Company then due and outstanding (including all debts due to any Member); then

4.2.2 The balance shall be distributed as follows:

a. To the Members in proportion to their Adjusted Capital Contributions, until their remaining Adjusted Capital Contributions have been paid in full; and

b. The balance, to the Members pro-rata in accordance with their percentage Interest.

4.3 **Distribution of Cash Flow**. The Cash Flow of the Company shall be distributed to the Members in accordance with their percentage Interest.

4.4 **Allocation of Profits and Losses**. After giving effect to the special allocations set forth in Section 4.5, Profits and Losses shall be allocated to the Members in accordance with their percentage Interest, provided that no Member shall be allocated a Loss that creates or increases an Adjusted Capital Account Deficit for such Member.

4.5 **Regulatory Allocations**.

4.5.1 **Minimum Gain Chargeback**. Except as set forth in Section 1.704-2(f) of the Regulations, if, during any taxable year, there is a net decrease in Minimum Gain, then each Member, prior to any other allocation under this Section 4.5, shall be specially allocated items of gross income and gain for such taxable year (and, if necessary, subsequent taxable years) in an amount equal to that Member's share of the net decrease of Minimum Gain, computed in accordance with Section 1.704-2(g) of the Regulations. Allocations of gross income and gain under this Section 4.5.1 shall be made first from gain recognized from the disposition of Company assets subject to Nonrecourse Liabilities, to the extent of the Minimum Gain attributable to those assets, and thereafter, from a pro-rata portion of the Company's other items of income and gain for the taxable year. It is the intent of the parties that any allocation under this Section 4.5.1 shall constitute a "minimum gain chargeback" under Section 1.704-2(f) of the Regulations.

4.5.2 **Member Minimum Gain Chargeback**. Except as otherwise provided in Section 1.704-2(i)(4) of the Regulations, if, during any taxable year, there is a net decrease in Member Minimum Gain attributable to a Member Nonrecourse Liability during any taxable year, then each Member who has a share of the Member Minimum Gain attributable to such Member Nonrecourse Liability shall be specially allocated items of gross income and gain for such taxable year (and, if necessary, subsequent taxable years) in an amount equal to that Member's share of the net decrease in the Member Minimum Gain. This allocation shall be made after the allocation under Section 4.5.1, and prior to any other allocation under this Section 4.5. Allocations of gross income and gain under this Section 4.5.2 shall be made first from gain recognized from the disposition of Company assets subject to Member Nonrecourse Liabilities to the extent of Member Minimum Gain attributable to those assets, and thereafter, from a pro-rata portion of the Company's other items of income and gain for the taxable year. It is the intent of the parties that any allocation under this Section 4.5.2 shall constitute a "minimum gain chargeback" under Section 1.704-2(i) of the Regulations.

4.5.3 **Qualified Income Offset**. If any Member unexpectedly receives any adjustments, allocations, or distributions described in Section 1.704-1(b)(2)(ii)(d)(4), Section 1.704-1(b)(2)(ii)(d)(5), or Section 1.704-1(b)(2)(ii)(d)(6) of the Regulations, then items of gross income and gain shall be specially allocated to each such Member in an amount and manner sufficient to eliminate, to the extent required by the Regulations, the Adjusted Capital Account Deficit of such Member as quickly as possible. An allocation under this Section 4.5.3 shall be made only if and to the extent that such Member would have an Adjusted Capital Account Deficit after all other allocations provided for under this Section 4.5 have been tentatively made as if this Section 4.5.3 were not in the Agreement.

4.5.4 **Nonrecourse Deductions**. Nonrecourse Deductions for a taxable year or other period shall be specially allocated among the Members on a pro-rata basis in accordance with their percentage Interest.

4.5.5 **Member Nonrecourse Deductions**. Any Member Nonrecourse Deduction for any taxable year or other period shall be specially allocated to the Member who bears the risk of loss with respect to the Member Nonrecourse Liability to which the Member Nonrecourse Deduction is attributable, as determined in accordance with Section 1.704-2(b) of the Regulations.

4.5.6 **Code Section 754 Adjustment**. To the extent an adjustment to the tax basis of any Company asset under Code Section 734(b) or Code Section 743(b) is required, under Section 1.704-1(b)(2)(iv)(m) of the Regulations, to be taken into account in determining Capital Accounts, the amount of the adjustment to the Capital Accounts shall be treated as an item of gain (if the adjustment increases the basis of the asset) or loss (if the adjustment decreases basis), and the gain or loss shall be specially allocated to the Members in a manner consistent with the manner in which their Capital Accounts are required to be adjusted under that section of the Regulations.

4.5.7 **Contributed Property and Book-Ups**. In accordance with Code Section 704(c) and the Regulations thereunder, as well as Section 1.704-l(b)(2)(iv)(d)(3) of the Regulations, income, gain, loss, and deduction with respect to any property contributed (or deemed contributed) to the Company shall, solely for tax purposes, be allocated among the Members so as to take account of any variation between the adjusted basis of the property to the Company for federal income tax purposes and its fair market value at the date of contribution (or deemed contribution). If the adjusted book value of any Company asset is adjusted as provided herein, then subsequent allocations of income, gain, loss, and deduction with respect to the asset shall take account of any variation between the adjusted basis of the asset for federal income tax purposes and its adjusted book value in the manner required under Code Section 704(c) and the Regulations thereunder. Allocations under this Section 4.5.7 are solely for the purpose of federal, state, and local taxes, and shall not be taken into account in determining any Member's Capital Account and allocable share of Profits and Losses.

4.5.8 **Withholding**. All amounts required to be withheld under Code Section 1446 or any other provision of Applicable Law shall be treated as amounts actually distributed to the affected Members for all purposes under this Agreement.

4.6 **Liquidation and Dissolution**.

4.6.1 If the Company is liquidated, then the assets of the Company shall be distributed in accordance with Article VII.

4.6.2 No Member shall be obligated to restore a Negative Capital Account.

4.7 **General**.

4.7.1 Except as otherwise provided in this Agreement, the timing and amount of all distributions shall be determined by the Manager. Notwithstanding the foregoing, to the extent permitted by law, the Company shall endeavor to make such minimum distributions at such times during the calendar year as enables the Members to use such distributions to satisfy, when due, their estimated and final income tax liabilities by reason of income allocated to the Members by the Company for the calendar year.

4.7.2 If any assets of the Company are distributed in kind to the Members, then those assets shall be valued at their fair market value, and any Member entitled to any interest in those assets shall receive that interest as a tenant-in-common with all other Members so entitled. Unless otherwise determined by the Manager, the fair market value of the assets shall be determined by an independent appraiser who shall be selected by the Manager. The Profit or Loss for each unsold asset shall be determined as if the asset had been sold at its fair market value, and the Profit or Loss shall be allocated as provided in Section 4.4 and shall be properly credited or charged to the Capital Accounts of the Members prior to the distribution of the assets.

4.7.3 All Profits and Losses shall be allocated, and all distributions shall be made to the Persons shown on the records of the Company to have been Members as of the last day of the taxable year for which the allocation or distribution is to be made. Notwithstanding the foregoing, unless the Company's taxable year is otherwise separated into two or more short years, if there is a Transfer during the taxable year, the Profits and Losses shall be allocated between the original Member and the successor on the basis of the number of days each was a Member during the taxable year.

4.7.4 The Manager is hereby authorized, upon the advice of the Company's tax counsel, to amend this Article IV to comply with the Code and the Regulations promulgated under Code Section 704(b); provided, however, that no amendment shall materially affect distributions to a Member without the Member's prior written consent.

ARTICLE V
Governance

5.1 **Manager**.

5.1.1 **Management**. The management and the control of the Company shall be vested in the Manager. Manager shall initially be Brian Truax. If Brian Truax is no longer the Manager, Tyler Truax shall be appointed Manager indefinitely. If either Brian Truax or Tyler Truax are unable to serve as Manager, a new Manager shall be elected by a majority vote of the Members. Any Manager, except Brian Truax, may be removed for "Cause," as defined herein, by a majority vote of the Members. For purposes of this Section 5.1.1 Cause shall be defined as, (i) a material breach of the

Manager's fiduciary duty; (ii) conviction of the Manager of a felony or crime of moral turpitude; and (iii) exclusion from participation in federal healthcare programs. Except as otherwise provided in this Agreement or Applicable Law (including, without limitation, the Act), the Manager shall have the full, exclusive, and absolute right, power and authority to manage and control the business, property and affairs of the Company. The Manager may bind and otherwise act as an agent of the Company in relation to third parties and outside affairs. Without limiting the generality of the foregoing, the Manager shall have the power and authority to:

a. Make expenditures for the benefit of the Company and to incur obligations on behalf of the Company in order to implement the business and purposes of the Company;

b. Employ or retain Persons, including any Member and any affiliate of any Member, whether full-time or part-time, at the expense of the Company, to perform services in connection with the operation and management of the Company's business on such terms and for such compensation as the Manager shall determine, in its sole and absolute discretion;

c. Negotiate, do any act, or enter into or execute and deliver, in furtherance of any or all of the purposes of the Company, any and all agreements, contracts, documents, certifications and other instruments of any nature deemed necessary, convenient or desirable in connection with the business and affairs of the Company, all of which may contain such terms, provisions and conditions as the Manager, in its sole and absolute discretion, shall deem appropriate;

d. Sell, exchange, convey, trade, surrender, release, abandon or otherwise dispose of all or any part of the assets of the Company, at such price or amount, for cash, securities or other property, and upon such terms and conditions as the Manager, in its sole and absolute discretion, deems advisable, appropriate or convenient and to be in the best interests of the Company;

e. Use the funds of the Company, including the Capital Contributions and borrowings, if any, for any purposes and on any terms that the Manager, in its sole and absolute discretion, determines to be appropriate, including without limitation, the costs of conducting the business and activities of the Company, the payment of its obligations and the repayment of its borrowings, if any;

f. Borrow money and incur indebtedness required for the business and affairs of the Company and, if security is required therefor, to secure the repayment of such borrowings by executing mortgages or deeds of trust, pledging or otherwise encumbering or subjecting to security interests, all or any part of the assets of the Company; obtain replacements of any loan, and repay, in whole or in part, refinance, increase, modify, consolidate, or extend the maturity of any indebtedness created by such borrowings, or any such mortgage, deed of trust, pledge, encumbrance, or other security device, all upon such terms as the Manager deems, in its sole and absolute discretion, to be in the best interests of the Company;

g. Acquire and enter into any contract of insurance which the Manager deems necessary or appropriate for the protection of the Company or for the conservation of Company assets;

h. Prepare or cause to be prepared reports, statements and other relevant information for dissemination to Members;

i. Open accounts and deposit and maintain funds in the name of the Company in banks, trust companies or securities broker-dealers and designate the signatories thereon; provided, however, that the Company's funds shall not be commingled with the funds of any other Person;

j. Establish a record date with respect to all actions to be taken hereunder that require a record date be established, including with respect to allocations and distributions; and

k. Bring and defend on behalf of the Company actions and proceedings at law or in equity before any court or governmental, administrative or other regulatory agency, body or commission or otherwise.

The expression of any power or authority of the Manager in this Agreement shall not in any way limit or exclude any other power or authority which is not specifically or expressly set forth in this Agreement.

5.1.2 **Limitations**. Notwithstanding the foregoing, the Manager shall not undertake any of the following actions without a Supermajority Vote of the Members:

a. Selling, leasing, exchanging or otherwise disposing of all, or substantially all, of the Company's property and/or assets outside the ordinary course of activities of the Company;

b. Approving a merger, conversion or domestication;

c. Dissolving or liquidating the Company;

d. Amending or modifying this Agreement or the Certificate of Organization, except as otherwise permitted herein;

e. The creation, incurring or assumption of any indebtedness for borrowed money by or on behalf of the Company that requires the personal guarantees of the Members;

f. The acquisition of any equipment, real or personal property by or on behalf of the Company having a cost or value in excess of Ten Thousand Dollars ($10,000.00);

g. Any other actions outside the ordinary course of activities of the Company; or

h. Filing of a voluntary petition for relief by the Company under any provision of the United States Bankruptcy Code or any similar or other law relating to bankruptcy, insolvency, reorganization, or other similar relief.

5.1.3 **Duties; Outside Activities**. The Manager shall devote to the Company's business such time as is necessary for the proper performance of the Manager's duties. Except as otherwise provided in this Agreement (including, without limitation, Article X), a Manager: (a) shall have no exclusive duty to act on behalf of the Company; (b) may have other business interests and may engage in other activities in addition to those relating to the Company; and (c) shall not incur any liability to the Company or to any of the Members as a result of engaging in any other business or venture. Neither the Company nor any Member shall have the right, by virtue of this Agreement, to share or participate in any other investments or activities of the Manager or to the income or profits derived therefrom.

5.1.4 **Transactions between a Manager and the Company**. A Manager does not violate a duty or obligation to the Company (fiduciary or otherwise) and a Manager shall not be liable to the Company, the Members or any other Person merely because the Manager's conduct furthers the Manager's own interests. A Manager may lend money to and transact other business with the Company, including, without limitation, entering into one or more agreements, leases, contracts or other arrangement with the Company for the furnishing of goods, services or space, provided that the rights and obligations of the Manager are substantially the same as those of a Person who is not a Manager. No transaction with the Company shall be voidable solely because a Manager has a direct or indirect interest in the transaction if a majority of the disinterested Members, knowing the material facts of the transaction and the Manager's interest, authorize, approve or ratify the transaction.

5.1.5 **Compensation**. Any Manager who is also a Member shall not be entitled to any consideration for services provided by that Manager on behalf of the Company, unless approved by a vote of the Members. However, the Company shall reimburse the Manager for all ordinary and necessary out-of-pocket expenses incurred by the Manager in his capacity as the Manager on behalf of the Company. If a Manager is appointed who is not also a Member, such Manager shall be entitled to reasonable compensation for his or her efforts in an amount to be mutually agreed upon between the non-Member Manager and the Members.

5.1.6 **Amendments by the Manager**. This Agreement may be amended by the Manager, without the consent or vote of the Members, if such amendment is: (a) for the purpose of clarification hereof and does not change the substance hereof; (b) necessary or appropriate, in the opinion of counsel for the Company, to comply with Applicable Law, provided such amendment does not adversely affect the interests of the Members; (c) necessary or advisable to comply with the Regulations or the Code, provided that such amendment does not adversely affect the interests of the Members; and (d) necessary or advisable to cure any ambiguity or to correct or to supplement any provisions hereof which may be inconsistent with any other provision hereof, provided such amendment does not adversely affect the interests of the Members.

5.2 **Members**.

5.2.1 **Authority**. Except as otherwise provided in this Agreement or required by any non-waivable provisions of the Act, a Member, in the Member's capacity as such, shall not have: (a) any power or authority to act for, or to undertake or assume any obligation or responsibility on behalf or in the name of the Company; or (b) any right to receive notice of, to be informed of, to participate in, to have any input into, to vote to approve or disapprove or to have any control over the business or affairs of the Company.

5.2.2 **Meetings of the Members**. A meeting of the Members may be called at any time by the Manager or the Member(s) holding at least forty-nine (49%) percent of the Units.

5.2.3 **Place of Meetings**. All meetings of the Members shall be held at the principal place of business of the Company or at such other place within the State of Minnesota as the Manager may select from time-to-time. Members may participate in a meeting by means of telephone conference, video conference or similar communications equipment provided that each Member participating in such meeting can hear the other participating Members. Such participation in a meeting will constitute presence in person at the meeting. If all Members are participating by telephone conference, video conference or similar communications equipment, the meeting will be deemed to be held at the principal place of business of the Company.

5.2.4 **Notice of Meetings**. Not less than five (5) nor more than thirty (30) days before each meeting of the Members, the Manager shall give written notice of the meeting to each Member entitled to vote at the meeting. The notice shall state the time, place and purpose of the meeting. Notwithstanding the foregoing, each Member who is entitled to notice shall be deemed to have waived notice if, before or after the meeting, the Member signs a waiver of the notice that is filed with the records of meetings, or is present at the meeting without objection.

5.2.5 **Quorum**. The presence, in person or via communication device described above, of the Manager and the Members holding the same or a greater percentage of Units as would be required necessary to effectuate the applicable vote shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the Members, the Members present may adjourn the meeting without notice other than announcement at the meeting and the meeting shall remain adjourned until a quorum is present, at which time it shall be re-convened.

5.2.6 **Voting**. Each Member shall have one (1) vote for each Unit (or fraction thereof) held by such Member on all matters being considered by the Members for which such Member is entitled to vote upon hereunder. Except as otherwise provided in this Agreement, the affirmative vote of at least a majority of the Units held by the Members entitled to vote shall be an act of the Members.

5.2.7 **Action without Meeting**. Any action or decision that may be made at a meeting of the Members also may be taken without a meeting, without prior notice and without a vote, pursuant to a written instrument or instruments indicating the consent of those Members holding the same or a greater percentage of Units as would be necessary to effectuate the applicable vote. A Member's written consent may be evidenced by such Member's signature on a counterpart of the proposal or by a separate writing (including a facsimile) that identifies the proposal with reasonable specificity and states that the Member consents to such proposal.

5.2.8 **Duties; Outside Activities**. Each Member shall devote to the Company's business such time as is necessary for the proper performance of the Member's duties. Except as otherwise provided in this Agreement, a Member: (a) shall have no exclusive duty to act on behalf of the Company; (b) may have other business interests and may engage in other activities in addition to those relating to the Company; and (c) shall not incur any liability to the Company or to any of the Members as a result of engaging in any other business or venture. Neither the Company nor any Member shall have the right, by virtue of this Agreement, to share or participate in any other investments or activities of any other Member or to the income or profits derived therefrom.

5.2.9 **Transactions between Members and Company**. A Member does not violate a duty or obligation to the Company (fiduciary or otherwise) and a Member shall not be liable to the Company, the Members or any other Person merely because the Member's conduct furthers the Member's own interests. A Member may lend money to and transact other business with the Company, including, without limitation, entering into one or more agreements, leases, contracts or other arrangement with the Company for the furnishing of goods, services or space, provided that the rights and obligations of a Member who lends money to or transacts business with the Company are substantially the same as those of a Person who is not a Member. No transaction with the Company shall be voidable solely because a Member has a direct or indirect interest in the transaction if a majority of the disinterested Members, knowing the material facts of the transaction and the Member's interest, authorize, approve or ratify the transaction.

5.2.10 **Termination for Cause**. Upon the occurrence of an event constituting Cause (as defined below), the Member (or Affiliated Individual of such Member) to whom such event has occurred shall immediately forfeit the Member's Interest, unless otherwise determined by the Manager. Each Member shall have an affirmative duty to notify the Company in writing within five (5) days after the occurrence of an event constituting Cause hereunder. For purposes of this Agreement, "Cause" means the occurrence of one or more of the following events:

a. A Member's or Affiliated Individual's (i) criminal indictment, (ii) participation in any dishonest act vis-a-vis the assets or income of Company or any Person with which Company is affiliated, whether or not of a criminal nature, (iii) participation in conduct having a reasonable prospect of materially damaging the reputation or integrity of Company or any Person with which Company is affiliated, (iv) participation in any act which materially impairs or jeopardizes Company's status under any agreement or contract Company has with any other Person;

b. A Member's attempt to Transfer the Member's Interest (or any part thereof) without the prior approval of the Manager as set forth herein;

c. A Member's failure to make a Capital Contribution or submit a personal guarantee in accordance with Article III;

d. A Member becoming a Bankrupt Member;

e. A Member's or Affiliated Individual's failure to abide by any the restrictive covenants set forth in Article IX or Article X;

f. A Member's material breach of any term, condition or covenant of this Agreement (except as set forth above), provided that such Member shall be entitled to thirty (30) days prior written notice, during which time the Member shall have the right to attempt to cure such breach to the reasonable satisfaction of Company; provided, however, that no advance notice shall be required if the breach is not reasonably likely to be cured within such thirty (30) day period.

5.3 **Limitation on Liability; Indemnification**.

5.4.1 **Limitation on Liability**. Except as otherwise required by any non-waivable provision of the Act or other Applicable Law, no Manager or Member will be personally liable in any manner whatsoever for any debt, liability or other obligation of the Company, whether such debt, liability or other obligation arises in contract, tort, or otherwise.

5.4.2 **Indemnification**. The Company, its receiver or its trustee will indemnify and hold harmless each Manager and Member (each an "Indemnified Party"), to the fullest extent permitted by Applicable Law, from and against any and all losses, damages, judgments, liabilities, costs and expenses (including reasonable attorneys' fees) arising from any claims, suits, demands or other proceeding in which the Indemnified Party may be involved, or threatened to be involved as a party or otherwise, relating to the performance or nonperformance of any act concerning the activities of the Company, if (i) the Indemnified Party acted in good faith and in a manner it believed to be in, or not contrary to, the best interests of the Company, and (ii) the Indemnified Party's conduct did not constitute gross negligence, willful misconduct or knowing violation of law. The termination of an action, suit or proceeding by judgment, order, settlement, or upon a plea of nolo contendere or its equivalent, will not, in and of itself, create a presumption or otherwise constitute evidence that the Indemnified Party acted in a manner contrary to that specified in clauses (i) or (ii) above. This Section will not be deemed to create any rights for the benefit of any other Person.

5.4.3 **Expenses**. The Company may advance to each Indemnified Party the costs of defending any claim, suit or action against such Indemnified Party if the Indemnified Party executes a written instrument, in the form approved by the Company, by which the Indemnified Party undertakes to repay the funds advanced, with interest, if it is determined by a court of competent jurisdiction that such Indemnified Party is not entitled to indemnification under Section 5.4.2.

ARTICLE VI
Transfers; Buy-Out

6.1 **Transfers to Third Parties**.

6.1.1 **Restrictions on Transfers**. Except as otherwise permitted by this Agreement, no Member may Transfer all or any portion of such Member's Interests, or grant or create any participation in such Member's right to receive distributions or returns of capital from the Company. Any purported Transfer in violation of this Section 6.1 shall be deemed null and void, and of no force or effect. Each Member hereby acknowledges the reasonableness of this provision in view of the purposes of the Company and the relationship of the Members. Any assignee desiring to

make a further Transfer will be subject to all of the provisions of this Section 6.1 to the same extent and in the same manner as any other Member desiring to make any Transfer.

6.1.2 **Permitted Transfers**. Notwithstanding the foregoing, a Member may Transfer all or a portion of the Member's Interest with the prior written consent of the Manager, which consent shall not be unreasonably withheld. Following the Transfer of a Member's entire Interest, the transferring Member shall have no further rights as a Member of the Company.

6.1.3 **Transfers by Operation of Law**. If, notwithstanding the provisions of this Section 6.1, any Person acquires all or any part of the Interest of a Member in violation of this Section 6.1 by operation of law, judicial proceeding or otherwise, the holder(s) of such Interest shall be an assignee and shall be entitled to receive only the share of income, gain, deductions, credits, and losses and the return of contributions to which said Member would otherwise be entitled ("Economic Rights"), and said Person will not be entitled or enabled to exercise any other rights or powers of a Member, including, without limitation, the right to vote on matters coming before the Manager or Members, grant approvals or give consents with respect to such Interest, the right to require any information or accounting of the Company's business, the right to receive any notices provided under this Agreement, the right to inspect the Company's books and records, or have any other rights of a Member under this Agreement or the Act ("Membership Rights").

6.1.4 **Substituted Members**. No assignee or transferee of a Member's Interest shall become a Member unless the following conditions are satisfied:

a. The Interest to which the assignee or transferee is admitted was acquired by means of Transfer permitted under this Agreement; and

b. The assignee or transferee agrees to bear all costs and expenses, including legal fees, of the Company incurred in effecting such substitution; and

c. The assignee or transferee becomes a party to this Agreement as a Member and executes such documents and instruments as the Company may reasonably request as necessary or appropriate to confirm such assignee or transferee as a Member in the Company and such assignee's or transferee's agreement to be bound by the terms and conditions of this Agreement; and

d. The assignee or transferee furnishes copies of all instruments effecting the transfer, opinions of counsel and such other certificates, instruments and documents as the Company may require.

6.1.5 **Rights of Transferees**. Until such time, if any, as an assignee or transferee of any Transfer pursuant to this Agreement is admitted to the Company as a Member pursuant to Section 6.1.4: (i) such assignee or transferee will only will receive, to the extent Transferred, the Economic Rights to which the Member that Transferred its Interest would be entitled; and (ii) such assignee or transferee will not be entitled or enabled to exercise any Membership Rights. Additionally, an assignee or transferee of any Transfer pursuant to this Agreement shall be obligated to make any

required Capital Contributions to which the Member that Transferred its Interest would be obligated to make in accordance with Article III.

6.1.6 **Disputed Transfers**. If the ownership of Units is in doubt, or if or there is reasonable doubt as to who is entitled to a distribution of the income realized from Units, the Company may accumulate the income until the issue is finally determined and resolved. Accumulated income will be credited to the capital account of the Member of record whose interest is in question.

6.2 **Buy-Out of a Selling Member**.

6.2.1 **Continuation**. The Company shall continue upon any Member becoming a Selling Member.

6.2.2 **Triggering Event**. In the event a Member becomes a Selling Member ("Triggering Event"), the Selling Member will be deemed to have offered to the remaining Members the Selling Member's entire Interest in the Company ("Offered Interest") within the timeframes and upon the other terms and conditions set forth in this Agreement.

6.2.3 **Member Option to Purchase**. The remaining Member(s) will have thirty (30) calendar days from receipt of written notice of the applicable Triggering Event within which to exercise, by written notice to the Manager ("Option Notice"), the option to purchase all or a portion of the Offered Interest at the Purchase Price (as set forth below). If more than one (1) remaining Member elects to purchase the Offered Interest, then each purchasing Member will have a right to purchase that portion of the Offered Interest that the number of Units held by such Member bears to the number of Units held by all of the Members electing to purchase the Offered Interest. Each Member electing to purchase will, within fifteen (15) days following receipt of the Option Notice, give notice to the Manager of the maximum portion of the Offered Interest that such Member is willing to purchase. If any Member elects to purchase less than such Member's pro-rata portion of the Offered Interest, the unpurchased portion of such Member's pro-rata portion may be purchased by any of the remaining Members. If more than one (1) Member is willing to purchase the remaining Offered Interest, then each Member will have the option to purchase that portion of the remaining Offered Interest that the number of Units held by such Member bears to the number of Units held by all Members electing to purchase the remaining Offered Interest. Notwithstanding the foregoing, the remaining Members may, by agreement among themselves, determine the proportion in which they will exercise the option granted in this Section 6.2.3.

6.2.4 **Company Option to Purchase**. If the entire Offered Interest is not purchased by the remaining Members, the Selling Member shall be deemed to have offered the remaining portion of the Offered Interest to the Company.

6.2.5 **Unpurchased Units**. If all of such Units are not purchased by the remaining Members and/or the Company, then the owner of such Units will only have Economic Rights with respect to such Units and shall continue to be obligated to make any required Capital Contributions the owner would be obligated to make in accordance with Article III.

6.2.6 **Purchase Price**. Subject to the limitations and reductions set forth herein, the purchase price payable to the Selling Member shall equal the Fair Market Value of the Company as of the Separation Date *multiplied by* a fraction, the numerator of which equals the number of Units held by the Selling Member which are subject to repurchase, and the denominator of which equals the total number of Units held by all of the Members (including the Selling Member) ("Purchase Price"); provided, however, that if the Selling Member is terminated for Cause pursuant to Section 3.4.2, then the Purchase Price payable to such Selling Member shall be reduced by the Selling Member's Available Commitment.

6.2.7 **Closing**. Except as otherwise provided in this Agreement, the closing of the purchase and sale of an Offered Interest ("Closing") shall take place on a date designated by Company ("Closing Date") in a written notice to the Selling Member, which shall occur no later than ninety (90) days after the date on which written notice to exercise the option is given.

6.2.8 **Closing Deliverables**. At the Closing, the Selling Member shall deliver the following: (a) good, valid and marketable title to the Offered Interest, free and clear of all liens, adverse claims, pledges, security interests, charges and encumbrances of any kind; (b) a certificate or certificates representing the Offered Interests being purchased endorsed by the Selling Member, if applicable; (c) a written resignation of the Selling Member as an officer, manager and Member of the Company, as applicable; and (d) such other documents which the Company shall deem reasonably necessary to effectuate the sale of the applicable portion of the Offered Interest.

6.2.9 **Power of Attorney**. Each Member hereby grants the Company an irrevocable power of attorney for the sole purpose of executing such documents as may be necessary and or desirable to evidence the sale of the Offered Interest if the Selling Member fails to do so in accordance herewith.

6.2.10 **Payment of the Purchase Price**. Each Purchaser may elect to pay all or a portion of the Purchase Price to the Selling Member on the Closing Date. Subject to the terms and conditions of this Agreement, to the extent not paid on the Closing Date, each Purchaser shall pay the remaining balance of the Purchase Price in sixty (60) equal and consecutive monthly installments of principal, *plus* interest at the minimum rate necessary to avoid imputed interest under the Internal Revenue Code, beginning on the first (1st) business day of the third (3rd) month succeeding the month in which the Closing takes place, and continuing on or before the fifteenth (15th) day of each month thereafter until paid in full; provided, however, that the Purchaser(s) shall have the right to prepay all or any part of the principal amount, together with any accrued interest thereon, at any time, without premium or penalty. If a Purchaser shall fail to pay any installment of the Purchase Price within thirty (30) days of the date due, the Selling Member may, after providing written notice to such Purchaser of such default and affording such Purchaser an additional ten (10) days to cure such default, accelerate payment and declare the entire unpaid principal balance, together with accrued interest, immediately due and payable by giving written notice to such Purchaser of such acceleration. Any installments of the Purchase Price not made within thirty (30) days of date due shall bear interest at the rate of one (1%) percent per month. Additionally, the defaulting Purchaser shall be responsible for reimbursing the Selling Member for all costs and expenses incurred by the Selling Member in connection with enforcing the Selling Member's rights to collect the Purchase Price hereunder, including, without limitation, reasonable attorneys' fees.

6.2.11 **Proxy**. During the period beginning on the Separation Date and ending with the Closing Date, this Agreement shall be deemed to be a proxy from the Selling Member to the remaining Member or the remaining Members, as the case may be, to vote the Units owned by the Selling Member on the Separation Date at any and all meetings of Members, whether annual or special. Each remaining Member shall have the right to vote a number of the Units owned by the Selling Member on the Separation Date equal to the product of: the total amount of Units owned by the Selling Member on that date *multiplied by* a fraction, the numerator of which shall equal the amount of Units then owned by that remaining Members, and the denominator of which shall equal the total amount of Units then owned by all of the remaining Members. Each remaining Member shall have the full and complete right to vote such Units at the Member's sole discretion and as the Member shall determine with respect to all matters which may come before such meetings, except that the remaining Member shall not have the right to vote such Units to reduce the rights of the Selling Member.

6.2.12 **Payment on Death**. If a Selling Member dies before the payments of the Purchase Price have been completed, then the Purchaser(s) shall pay the balance of such payments to the legal representative of the Selling Member in the same amounts and under the same terms as would have otherwise been payable to such Selling Member pursuant to this Agreement.

6.2.13 **Offsets**. The Company shall have the right to offset against the payment or payments of the Purchase Price due to the Selling Member, any negative Capital Account balances of the Selling Member, the amount of all loans or other indebtedness due from the Selling Member to the Company, and to the extent so credited against the Purchase Price, such obligations of the Selling Member shall be deemed to be and shall be canceled and discharged. All such offsets against the Purchase Price owed to the Selling Member shall be made regardless of the due date of any such loan or other indebtedness.

6.2.14 **Adjustment for Pre-Paid Expenses**. The Purchase Price shall be reduced by the amount of any expenses and benefits paid by the Company for the benefit of a Selling Member which relate to the period after the Selling Member's Separation Date.

6.2.15 **Deficit**. In the event the amounts owed by a Selling Member to the Company exceed the Purchase Price and any other amounts payable to such Selling Member ("Deficit"), the Selling Member shall pay such Deficit to the Company within thirty (30) days of the Closing Date.

6.2.16 **Forfeiture**. The provisions of this Section 6 and all payments hereunder are conditioned upon the Selling Member abiding by the restrictive covenants set forth in this Agreement. Any breach by the Selling Member of any restrictive covenants shall make the obligation of the Company to make any further payments of the Purchase Price null and void, and the Selling Member shall be required to repay a sum equal to any payments of the Purchase Price previously received by the Selling Member hereunder.

6.2.17 **No Voluntary Withdrawal of Member**. No Member shall have the right to voluntarily withdraw as Member.

6.2.18 **Relief**. The repurchase of all or any portion of the Offered Interest of a Selling Member under this Section 6 does not preclude the Company from seeking injunctive relief, monetary damages or any other legal remedies to which the Company is entitled due to the actions of the Selling Member or failure to comply with the restrictive covenants set forth in Article IX or Article X.

6.2.19 **Drag-Along Rights**.

a. If the Manager approves the sale of all, or less than all, of the Units held by all of the Members (the "Collective Interests") to a third party in a single transaction or series of transactions, then the Manager shall deliver a written notice ("Sale Notice") to the Members which states the material terms and conditions of the proposed sale (including, without limitation, the total purchase price, and the name, business and residence address of the proposed purchaser(s)) and shall have attached any documentation related to the proposed sale.

b. Upon providing the Sale Notice, the Manager shall have the right to require all of the Members to sell all or a pro-rated portion of their Units according to the same terms and conditions according to the terms and conditions set forth in the offer approved by the Manager, subject to appropriate adjustment for lack of voting rights and for other preferences and privileges set forth herein. The Manager shall arrange for the proposed purchaser to purchase such Units from the Members according to the same terms and conditions as set forth in Sale Notice. The Members hereby agree and covenant to enter into the appropriate sales documents, amended operating agreement of the Company and other documents related to the transaction, as may be required to effectuate the transaction. Failure to abide by the terms of this provision shall be grounds for termination for Cause. Notwithstanding the foregoing, each of the Members hereby grants the Company an irrevocable power of attorney to enter such agreements and documents on behalf of such Member, or as are reasonably required to effectuate the sale of the Collective Interests.

ARTICLE VII
Dissolution and Liquidation

7.1 **Events of Dissolution**. The Company shall be dissolved upon the occurrence of any of the following events:

7.1.1 Upon the Supermajority Vote of the Members, including the written consent of the sole remaining Member of the Company; or

7.1.2 Any other event causing the dissolution of the Company under the laws of the State of Minnesota, unless provided otherwise herein.

7.2 **Continuation**. Notwithstanding any other provision of this Agreement, upon the occurrence of any of the events specified in Section 7.1, the business of the Company may be continued by the Supermajority Vote of the Members within ninety (90) days of the occurrence of such event.

7.3 **Winding-Up**.

7.3.1 Upon the dissolution of the Company requiring the winding-up of its affairs, the Manager shall wind up its affairs. The assets of the Company shall be sold within a reasonable period of time to the extent necessary to pay or provide for the payment of all debts and liabilities of the Company, and may be sold to the extent deemed practicable and prudent by the Manager.

7.3.2 The Manager shall file, or cause to be filed, all certificates or notices of the dissolution of the Company as required by Applicable Law and perform any other acts necessary or appropriate to wind up the affairs of the Company. Upon the complete liquidation and distribution of the property and assets of the Company, the Members shall cease to be Members of the Company, and the Members shall execute, acknowledge and cause to be filed all certificates and notices required by Applicable Law to terminate the Company.

7.4 **Distributions**. The net proceeds resulting from the liquidation of the assets of the Company shall be distributed in accordance with the following priorities:

7.4.1 First, to the payment, to the extent required by any lender or creditor, of accrued expenses, debts, obligations and liabilities of the Company;

7.4.2 Second, to the setting up of any Reserve which the Manager deems necessary to provide for any contingent or unforeseen liabilities or obligations of the Company; provided, however, that at the expiration of such period of time as the Manager deems advisable, the balance of such Reserve shall be distributed in the manner hereinafter set forth in this Section 7.4;

7.4.3 Third, to Members to repay any loans or advances made by them to the Company; and

7.4.4 Fourth, the balance shall be distributed to the Members on a pro-rata basis in accordance with their percentage Interest.

7.5 **Distributions to Members**. Distributions to Members pursuant to this Article VII shall be made by the end of the taxable year of the liquidation, or, if later, ninety (90) days after the date of such liquidation in accordance with Regulations.

ARTICLE VIII
Books, Records, Accounting, and Tax Elections

8.1 **Bank Accounts**. All funds of the Company shall be deposited in a bank account or accounts opened in the Company's name. The Manager shall determine the institution or institutions at which the accounts will be opened and maintained, the types of accounts, and the Persons who will have authority with respect to the accounts and the funds therein.

8.2 **Books and Records**.

8.2.1 The Manager shall keep, or cause to be kept, complete and accurate books and records of the Company and supporting documentation of the transactions with respect to the conduct of the Company's business. The records shall include, but not be limited to: (a) complete

and accurate information regarding the state of the business and financial condition of the Company; (b) a copy of the Certificate of Organization and this Agreement, all amendments to the Certificate of Organization and this Agreement, and all executed copies of any written powers of attorney pursuant to which this Agreement, any certificate, and all amendments thereto have been executed; (c) a current list of the names and last known business, residence, or mailing addresses of all Members and the dates they became Members; (d) the Company's federal, state, and local tax returns; and (e) true and full information regarding the amount of cash and a description and statement of the agreed value of any other property or services contributed by each Member and which each Member has agreed to contribute in the future.

8.2.2 The books and records shall be maintained in accordance with sound accounting practices and shall be available at the Company's principal office for examination by any Member or the Member's duly authorized representative at any and all reasonable times during normal business hours. The Manager shall have the right to impose reasonable limitations on a Member's right to access books and records, including the type of records accessible to such Member.

8.2.3 Any request for information shall be in writing, and shall state the purpose therefor. Each Member shall reimburse the Company for all costs and expenses incurred by the Company in connection with the Member's inspection and copying of the Company's books and records.

8.3 **Annual Accounting Period**. The annual accounting period of the Company shall be its taxable year. The Company's taxable year shall be selected by the Manager, subject to the requirements and limitations of the Code.

8.4 **Reports**. Within ninety (90) days after the end of each taxable year of the Company or as soon thereafter as reasonably practicable, the Manager, at the Company's cost and expense, shall use commercially reasonable efforts to cause to be prepared and sent to each Person who was a Member at any time during the accounting year then ended such information concerning the Company which is necessary for the preparation of the Person's income tax returns for that year. All such teports shall be at the expense of the Company. At the request of any Member and at such Member's expense, a Member may cause an audit of the Company's books and records to be prepared by independent accountants for the period requested by the Member.

8.5 **Tax Matters Partner**. The Manager may appoint a Tax Matters Partner of the Company pursuant to Code Section 6231(a)(7). Tax Matters Partner shall take such action as may be necessary to cause, to the extent possible, each Member to become a "notice partner" within the meaning of Code Section 6223. Tax Matters Partner shall inform each Member of all significant matters that may come to his or her attention in his or her capacity as such by giving notice thereof on or before the fifth (5^{th}) business day after becoming aware thereof and, within that time, shall forward to the Members copies of all significant written communications the Member may receive in that capacity. Tax Matters Partner, in his or her capacity as such, shall take no action without the authorization of the Manager, other than such action as may be required by Applicable Law. Any cost of expense incurred by Tax Matters Partner in connection with his or her duties as "tax matters partner," including the preparation for administrative or judicial proceedings, shall be paid by the Company.

8.6 **Tax Elections**. The Manager shall have the authority to make all Company elections permitted under the Code, including, but not limited to, elections of methods of depreciation and elections under Code Section 754. The decision to make or not make an election shall be at the sole and absolute discretion of the Manager.

ARTICLE IX
Confidentiality

9.1 **Non-Disclosure**. Each Member and each Affiliated Individual of a Member acknowledges that they will have access to certain information and data that is confidential and proprietary to the Company. Accordingly, each Member and Affiliated Individual covenants and agrees that, during the period of time the Member is a party to this Agreement and at all times thereafter, such Person shall (a) hold in strict confidence and safeguard the Company's Confidential Information, (b) not disclose, disseminate or make available to any third party the Company's Confidential Information, and (c) not use, copy or otherwise benefit from the Company's Confidential Information, except to their respective duly authorized representatives who need to know such Confidential Information in connection with the transactions contemplated by this Agreement or in connection with the Member's performance of duties or exercise of rights under this Agreement. Each Member and each Affiliated Individual of a Member will use all reasonable efforts to cause their respective duly authorized representatives to treat all Confidential Information as confidential, preserve the confidentiality of such Confidential Information and not disclose any Confidential Information. Each Member and each Affiliated Individual of a Member will be responsible for any breach of this Agreement by any of their respective duly authorized representatives. If Confidential Information is disclosed, the Member responsible for such disclosure will immediately notify the Company in writing and take all reasonable steps required to prevent further disclosure.

9.2 **Title to Confidential Information**. Each Member and each Affiliated Individual of a Member acknowledges and agrees that all Confidential Information shall be the sole and exclusive property of the Company. This Agreement shall not confer upon any Member or any Affiliated Individual (or their respective representatives), or be a basis for implying, any license, interest or rights of any kind in or to the Confidential Information of the Company. In the event a Member becomes a Selling Member, or as soon as possible following Company's written request, the Member and each Affiliated Individual of such Member shall immediately return to the Company any and all Confidential Information that they may have in their possession, and any copies thereof in any format.

9.3 **Disclosures Required by Law**. If a Member or Affiliated Individual of a Member becomes legally obligated to disclose any Confidential Information, such Person shall provide the Company with prompt written notice so that the Company may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Article IX. If such protective order or other remedy is not obtained, or if the Company waives compliance with the provisions of this Article IX, the Member or Affiliated Individual of the Member shall furnish only that portion of Confidential Information which it is legally required to disclose.

9.4 **Restrictions on Access**. Notwithstanding anything herein to the contrary, the Manager shall have the right to keep confidential from the Members, for such period of time as the

Manager deems reasonable, any information which (a) the Manager believes to be in the nature of trade secrets or other information the disclosure of which the Manager believes is not in the best interests of the Company or could damage the Company or its business, or (b) the Company is required by Applicable Law or by agreement with a third party to keep confidential. The Manager may require, as a condition to giving any Person access to any confidential information, that such Person enter into a confidentiality agreement with the Company in a form and substance satisfactory to the Manager.

9.5 **Remedies**. In light of the sensitive and proprietary nature of the Confidential Information protected hereunder, each Member acknowledges and agrees that the Company shall be entitled to enforce this Article IX by seeking an injunction to enjoin and restrain the unauthorized disclosure or use of its Confidential Information. Nothing herein shall be construed as limiting the Company's right to seek any other remedies available to the Company for a Member's or Affiliated Individual's breach or threatened breach of this Article IX, including, without limitation, monetary damages. In the event a Member or Affiliated Individual of a Member breaches this Article IX, such Member and each Affiliated Individual of such Member shall be jointly and severally responsible for reimbursing the Company for all costs and expenses incurred by or on behalf of the Company in connection with enforcing its rights hereunder, including, without limitation, reasonable attorneys' fees, filing fees, arbitration fees, court fees, expert witness fees, and litigation and pre-litigation expenses.

ARTICLE X
Miscellaneous Provisions

10.1 **Notifications**. Any notice, demand, consent, election, offer, approval, request, or other communication (collectively a "notice") required or permitted under this Agreement must be in writing and either delivered personally or sent by overnight express mail, certified or registered mail, postage prepaid, return receipt requested. A notice to a Member shall be addressed to the Member at the Member's address set forth on **Exhibit A** or such other address as a Member may designate from time-to-time by notice satisfactory under this Section. A notice to the Company shall be addressed to the Company's principal office. Notices given by mail shall be deemed effectively given on the earlier of the date shown on the proof of receipt of such mail or, unless the recipient proves that the notice was received later or not received, three (3) days after the date of mailing thereof.

10.2 **Specific Performance**. The parties recognize that irreparable injury will result from a breach of any provision of this Agreement and that money damages will be inadequate to remedy fully the injury. Accordingly, in the event of a breach or threatened breach of one or more of the provisions of this Agreement, any party who may be injured (in addition to any other remedies which may be available to that party) shall be entitled to seek one or more preliminary or permanent orders (a) restraining and enjoining any act which would constitute a breach or (b) compelling the performance of any obligation which, if not performed, would constitute a breach.

10.3 **Effect of Waiver or Consent**. The Company may give an express or implied waiver or consent to a specific breach or default by a Person of that Person's obligation to the Company. Any specific waiver or consent is not, however, a consent or waiver to any other breach or default in the Person's performance of the Person's same or other obligations to the Company. A Person's

failure to complain of any Person's acts or to declare any Person in default with respect to the Company does not waive that Person's rights with respect to that default until the applicable statute-of-limitations period has run.

10.4 **Complete Agreement**. This Agreement together with the Exhibits attached hereto constitutes the complete and exclusive statement of the agreement among the Members with respect to the subject matter hereof and shall supersede all prior written and oral statements, including any prior representation, statement, condition, or warranty, with respect to such subject matter.

10.5 **Applicable Law**. This Agreement, including its existence, validity, construction, and operating effect, and the rights of each of the parties hereto, will be governed by and construed in accordance with the laws of the State of Minnesota without regard to otherwise governing principles of conflicts of law. The Members waive any and all rights they may have to punitive, special, exemplary, or consequential damages, in respect of any dispute based on this Agreement.

10.6 **Arbitration**. Except for alleged breaches of Article IX or Article X, any controversy, dispute or disagreement arising out of or relating to this Agreement, the breach thereof, or the subject matter thereof, shall be settled exclusively by binding arbitration, by a single arbitrator, which shall be conducted in Beltrami County, Minnesota in accordance with the American Health Lawyers Association Alternative Dispute Resolution Service Rules of Procedure for Arbitration, and which to the extent of the subject matter of the arbitration, shall be binding not only on all parties to the Agreement, but on any other entity controlled by, in control of or under common control with the party to the extent that such affiliate joins in the arbitration, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. A party may initiate such arbitration by making written demand for arbitration on the other party. The demand shall contain a statement setting forth the nature of the dispute, the amount of damages involved, if any, and the remedies sought. The actual cost of the arbitration, including the fees of the arbitrator shall be borne equally by the parties.

10.7 **Titles and Captions**. All articles, section and paragraph titles and captions contained in this Agreement are for convenience only and do not define or limit the scope, extent, or intent of this Agreement or any of the provisions hereof.

10.8 **Use of Certain Terms**. All pronouns and any variations thereof are deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the persons may require. The words "include" and "including" shall be deemed to be followed by the phrase "without limitation"; and the terms "hereof," "herein" and "hereunder" and words of similar import shall be deemed to refer to this Agreement (or such other cross-referenced document) as a whole and not to any particular provision, unless the context clearly indicates otherwise.

10.9 **Binding Effect**. This Agreement is binding upon, and inures to the benefit of, the parties hereto and their respective heirs, executors, administrators, personal and legal representatives, successors, and permitted assigns.

10.10 **No Third Party Rights**. None of the provisions of this Agreement shall be construed for the benefit of, or enforceable by, any of the creditors of the Company or any creditors of the Members, or any other Person not a party to this Agreement.

10.11 **Severability**. If any provision of this Agreement shall be deemed by a court of competent jurisdiction to be legally invalid or unenforceable, then the validity and enforceability of the remainder of the Agreement shall not be affected and such provision shall be deemed modified to the minimum extent necessary to make such provision consistent with Applicable Law, and, in its modified form, such provision shall then be enforceable.

10.12 **Counterparts; Attestation**. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all the parties reflected herein as the signatories. Signatures transmitted by facsimile or pdf/email transmission shall be deemed originals for this purpose. The absence of a witness's signature, if such signature is required hereunder, shall not defeat or undermine the execution hereof or the validity of a party's signature as long as each party's respective signature is affixed to the signature page hereof.

10.13 **Representation and Warranty**. Each Member hereby represents, warrants and covenants that such Member has the right and authority to enter into this Agreement and that the Member's execution hereof and performance hereunder will not violate, conflict with, result in the breach of, or constitute default under, any agreement or arrangement to which the Member is a party or subject to. Such Member shall indemnify, defend and hold the Company and its Members harmless from and against any and all claims, losses, liabilities, damages, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising from or relating to any inaccuracy or breach of any of the foregoing representations and warranties.

10.14 **Further Assurances**. Each of the Members hereto does hereby covenant and agree on behalf of itself, its successors, and its assigns, without further consideration, to prepare, execute, acknowledge, file, record, publish, and deliver such other instruments, documents and statements, and to take such other action as may be required by Applicable Law or reasonably necessary to effectively carry out the purposes of this Agreement.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date set forth above.

COMPANY:

TRUAX PATIENT SERVICES, LLC

By: _____
Brian Truax, Manager

MEMBERS:

_____
Brian Truax

PH # (218) 444-8217
FAX # (218) 444-2267

TRUAX PATIENT SERVICES

NATIONAL SPECIALTY/MAIL ORDER PHARMACY
1112 RAILROAD ST SE STE#4, BEMIDJI, MN 56601

11/03/20

Sent via: FEDEX OVERNIGHT MAIL

NEVADA BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY, STE 206, RENO, NV 89521

Re: Truax Patient Services
Notification of Anticipated Change of Ownership

Dear Sir or Madam:

This letter is intended to inform the NEVADA Board of Pharmacy (the "Board") of a proposed change in the ownership structure of Truax Patient Services, located at 1112 Railroad Street SE, Suite 4, Bemidji, Minnesota 56601 (the "Pharmacy"). The Pharmacy's current state license number is PH02866, DEA registration number is FT5596676, and NABP e-profile identification number is 2431461. The Pharmacy is currently licensed in all U.S. states that require non-resident licensure, as well as Washington D.C.

It is the intent of the current sole proprietor of the Pharmacy, Brian W. Truax, to incorporate as a single member limited liability company with no other members, scheduled to take effect pursuant to a closing currently scheduled on or around the anticipated date of December 15, 2020, or as soon as possible thereafter, to the extent permitted by the Board.

In furtherance of the anticipated change in ownership structure, and to limit any downtime associated with the transition to a single member limited liability company, the Pharmacy has sought to provide the Board with advance notice of the anticipated change.

Attached please find the application and supporting documentation required for the applicable pharmacy permit based on the change of ownership. Please note we intend to supplement the application with applicable licenses issued to the limited liability company once approved by the various jurisdictions and agencies.

If you have any questions or require any further information, please feel free to contact me.

Respectfully submitted,

/s/ Brian W. Truax
Brian W. Truax

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy or* ☒ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** 02455

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: US MED, LLC

Physical Address: 1480 NW 79th Avenue, Miami, FL 33126

Mailing Address: 8260 NW 27th Street, Ste. #403 Attn: Licensing Department

City: Doral State: FL Zip Code: 33122

Telephone: (866) 938-4482 Fax: (866) 223-7369

Toll Free Number: (866) 938-4482 (Required per NAC 639.708)

E-mail: Licensing@usmed.com Website: www.usmed-rx.com

Managing Pharmacist: Terrell Bohannon License Number: PS49584

TYPE OF PHARMACY AND SERVICES PROVIDED BKMS, 6/29/21

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☐	☒ Other: _____	☐	☒ Sterile Compounding **
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding **
	For the application to be complete	☐	☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Timothy Cady
Print Name of Authorized Person

6/14/2021
Date

Board Use Only Date Processed: 6/25/21 Amount: $500 MO# ✓

19-27546459

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: US Med Acquisition, Inc.

Mailing Address: 8260 NW 27th Street, Ste. #401

City: Doral State: FL Zip: 33122

Telephone: 866-938-4482 Fax: 866-223-7369

Contact Person: Jessenia Rodriguez

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) US MED Acquisition, Inc. 8260 NW 27TH ST STE #401, Doral, FL 33122
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? Date of Sale: 7/21/2021

5) Provide a copy of the corporation's stock register evidencing the above information N/A

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 7:00 am 6:00 pm Saturday 8:00 am 12:00 pm

Sunday Closed am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

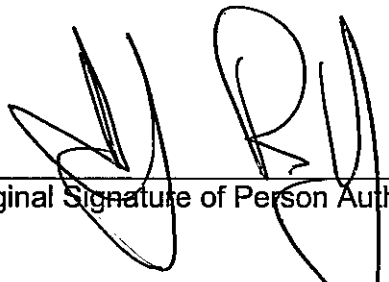
I, Timothy Cady

Responsible Person of US MED, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies of stamps

Timothy Cady
Print Name of Authorized Person

6/14/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
) ss.
San Diego COUNTY)

I, Timothy Cady, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President for US MED, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Timothy Cady, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
16th day of June, 2021.

Faafeai Seioliana Aano.
NOTARY PUBLIC

FAAFEAI SEIOLIANA AANO
Notary Public - California
San Diego County
Commission # 2356836
My Comm. Expires May 10, 2025

Department of Health

TERRELL WAYNE BOHANNON

License Number: PS49584

Data As Of 6/29/2021

Profession	Pharmacist
License	PS49584
License Status	CLEAR/ACTIVE
License Expiration Date	9/30/2021
License Original Issue Date	08/20/2012
Address of Record	1480 NW 79 Ave DORAL, FL 33126
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

AC# 9893176

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/07/2020	PH 23521	117721

THE **PHARMACY**

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy
6:1 Pharmacy Technician Ratio Approved

Expiration Date: **FEBRUARY 28, 2023**
US MED, LLC
1480 NW 79 AVE
ATNN: LICENSING DEPT.
MIAMI, FL - 33126

Ron DeSantis
GOVERNOR

Scott A. Rivkees, MD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

AC# 9893176

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
11/07/2020	PH 23521	117721

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : FEBRUARY 28, 2023

US MED, LLC

REGISTRANT SIGNATURE

QUALIFICATION(S):
Community Pharmacy
6:1 Pharmacy Technician Ratio
Approved

Department of Health

License Number: PH23521

Data As Of 6/10/2021

Profession	Pharmacy
License	PH23521
License Status	CLEAR/
Qualifications	Community Pharmacy Central Fill
License Expiration Date	2/28/2023
License Original Issue Date	07/30/2008
Address of Record	1480 NW 79 AVE ATNN: LICENSING DEPT. MIAMI, FL 33126
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

State of Florida
Department of State

I certify from the records of this office that US MED, LLC is a limited liability company organized under the laws of the State of Florida, filed on August 10, 2015, effective February 19, 1999.

The document number of this limited liability company is L15000134714.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on April 25, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifteenth day of June, 2021



Secretary of State

Tracking Number: 8426049219CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

US MED, LLC

List of Owners/Officers/Directors

Name	Title	Address
Timothy Cady	President	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Mark Howard	CEO	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Jeff Abramoff	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Kurt Hilzinger	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
John Weber	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
US Med Acquisition, Inc.	100% Owner	8260 NW 27TH ST STE 401 Doral, FL 33122

Medicaid Provider Numbers - US MED, LLC

State	Provider Number
Alabama	137917
Alaska	1624492
Arizona	580258
Arkansas	166398741
California	960140
Colorado	84857544
Connecticut	8048206
Delaware	1811097504
Florida	16979800
Georgia	003133088A
Hawaii	61-1339483 (594748)
Idaho	1811097504
Illinois	611339483001
Indiana	200972060A
Iowa	208753
Kansas	200737930A
Kentucky	7100038430
Louisiana	2349066
Maine	433081100
Maryland	330208300
Massachussets	110150820A
Michigan	4998747
Minnesota	637903000
Mississippi	8304576
Missouri	629630609
Montana	1811097504
Nebraska	10025519700
Nevada	1811097504
New Hampshire	3112960
New Jersey	580210
New Mexico	89339771
New York	3862815
North Dakota	1458965
Ohio	2766396
Oklahoma	200285920A
Oregon	218108
Pennsylvania	1026305880001
Rhode Island	4146440
South Carolina	DM1260
South Dakota	9164650
Tennessee	4582505
Texas	198070801
Utah	1811097504
Vermont	1015385
Virginia	1811097504
Washington	1025319
West Virginia	3910005911
Wisconsin	100050570
Wyoming	125360300

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/3/2021

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

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

PRODUCER Arthur J. Gallagher Risk Management Services, Inc. 9155 S Dadeland Blvd Suite 1112 Miami FL 33156	CONTACT NAME: PHONE (A/C, No, Ext): 305-592-6080 FAX (A/C, No): 305-592-4049 E-MAIL ADDRESS:
INSURED UNITSTA-31 US MED, LLC 1480 NW 79th Avenue Miami, FL 33126	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Arch Specialty Insurance Company — 21199 INSURER B : American Zurich Insurance Company — 40142 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 753923701 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			BAP 0184650-06	2/23/2021	2/23/2022	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 2,000,000
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$ 2,000,000
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC 0233413-05	2/23/2021	2/23/2022	X PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? ☐ N/A						E.L. EACH ACCIDENT	$ 1,000,000
	(Mandatory In NH)						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Misc Med Prof Prof Liab._Claims Made			FLP005820705	2/23/2021	2/23/2022	Occurence Aggregate	$1,000,000 $3,000,000

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

CERTIFICATE HOLDER

US MED, LLC
1480 NW 79th Ave
Miami FL 33126

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

1480 NW 79TH Ave, Miami, FL 33126
Phone: 877-345-5813 | Fax: 305-455-3587
Email: Licensing@usmed.com

June 15, 2021

Via FedEx

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: US MED, LLC - License # PH02455

Dear Sir or Madam:

This letter provides notice of a change in the indirect ownership of US MED, LLC which holds the above referenced Pharmacy permit. Effective July 21, 2021, US MED Buyer, inc. will become the sole shareholder of US MED Acquisition, Inc. the facility's parent company. The enclosed organizational chart shows the ownership structure after the transaction. As stated above, this change took place two levels above the operating entity.

Importantly US MED, LLC continues to be the direct owner of the facility. There has been a change in officer's, but the facility will:

- Retain the same EIN
- Retain the same name
- Retain the same location
- Retain the same pharmacist in charge
- Retain the same employees
- Retain the same Home State Pharmacy Permit Number

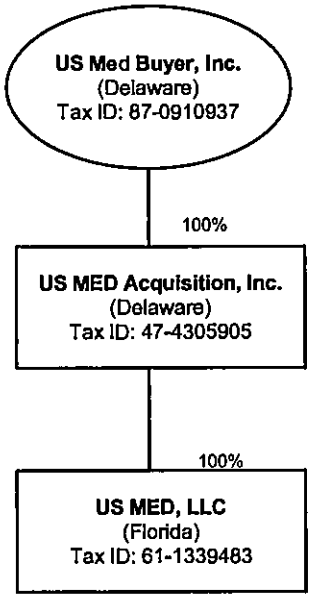
Please let us know if you require any additional information at licensing@usmed.com.

Sincerely,

Mary Ellen Conway

Mary Ellen Conway
Chief Compliance Officer

US MED, LLC – Post-Closing Structure Chart



40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

New Pharmacy or ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***
Check box below for type of ownership and complete all required forms.
Publicly Traded Corporation – Pages 1,2,3,8 *Partnership - Pages 1,2,6,8*
Non Publicly Traded Corporation – Pages 1,2,4,8 -LLC *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: XeCare LLC

Physical Address: 9750 Innovation Campus Way, New Albany, OH 43054

Mailing Address: 9750 Innovation Campus Way

City: New Albany State: OH Zip Code: 43054

Telephone: 1-855-918-4467 Fax: 833-302-1460

Toll Free Number: 1-855-918-4467 (Required per NAC 639.708)

E-mail: pharmacy@xecare.com Website: www.xecare.com

Managing Pharmacist: Daniel DiStefano License Number: 03439312 (OH)

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☑	Retail	☐	Off-site Cognitive Services
☐	Hospital (# beds____)	☐	Parenteral **
☐	Internet	☐	Parenteral (outpatient)
☐	Nuclear	☐	Outpatient/Discharge
☐	Ambulatory Surgery Center	☑	Mail Service
☐	Community	☐	Long Term Care
☐	Other: _____	☐	Sterile Compounding **
		☐	Non Sterile Compounding
All boxes must be checked		☐	Mail Service Sterile Compounding **
For the application to be complete		☐	Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Lori Jackson

Original Signature of Person Authorized to Submit Application, no copies or stamps

Lori Jackson

Print Name of Authorized Person

04/06/2021

Date

Board Use Only	Date Processed:	Amount: 500 661766657

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION - Ownership is an LLC

State of Incorporation: DE is State of Formation as this is an LLC

Parent Company if any: XeCare Holdings Inc.

Mailing Address: 9750 Innovation Campus Way

City: New Albany State: OH Zip: 43054

Telephone: 855-918-4467 Fax: 833-302-1460

Contact Person: Lori Jackson

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation? N/A-LLC no shares issued

a) _____
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A - LLC

3) What was the price paid per share? N/A - LLC

4) What date did the corporation actually receive the cash assets? N/A - LLC

5) Provide a copy of the corporation's stock register evidencing the above information N/A - LLC

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:00 am 5:00 pm Saturday Closed am _____ pm

Sunday Closed am _____ pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Lori Jackson, President

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Lori Jackson

Responsible Person of XeCare LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Lori Jackson

Original Signature of Person Authorized to Submit Application, no copies or stamps

Lori Jackson

Print Name of Authorized Person

04/06/2021

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Ohio)
) ss.
Franklin COUNTY)

I, Lori Jackson, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President for XeCare LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Lori Jackson, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
8th day of April, 2021.

NOTARY PUBLIC

NOTARIAL SEAL
STATE OF OHIO

Richard A. Raber
Notary Public, State of Ohio
My Commission Expires 06-06-23

Ohio | eLicense Ohio Professional Licensure

License Look Up

4/16/2021 4:51 PM

XeCare LLC

Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 2
License Number	0230000010
License Issue Date	10/23/2020
License Expiration Date	03/31/2023
License Effective Date	04/01/2021
Street Address	9750 Innovation Campus Way
City	New Albany
State	OH
Zipcode	43054
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
DANIEL DISTEFANO		Active	Mon Jun 15 00:00:00 GMT 2020	

Current date & time: **4/16/2021 4:51 PM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2023.

XeCare LLC

9750 Innovation Campus Way

New Albany, OH 43054

License Number: 0230000010

Terminal - Pharmacy - Category 2

Expiration Date: March 31, 2023

CLASS: Terminal - Pharmacy - Category 2
BUSINESS TYPE: MO – Mail order

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Daniel DiStefano	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "XECARE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINETEENTH DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

3070776 8300

SR# 20211349843

Authentication: 203001104

Date: 04-19-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* **PH**_____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☒ *Partnership - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Crimson Valley Pharmacy, LLC

Physical Address: 2351 S. River Road, Ste #3

Mailing Address: S/A

City: Saint George State: UT Zip Code: 84790

Telephone: 435-218-7744 Fax: 435-218-7743

Toll Free Number: 1-888-552-5090 (Required per NAC 639.708)

E-mail: crimsonvalleyrx@gmail.com Website: www.crimsonvalleyrx.com

Managing Pharmacist: Shawna Rechsteiner License Number: 10228906

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☒	☐ Retail	☐	☒ Off-site Dispensing
☐	☒ Hospital (# beds____)	☐	☒ Parenteral
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☐	☒ Other: _____	☐	☒ Sterile Compounding
		☒	☐ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding
	For the application to be complete	☐	☒ Other Services: _____

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes" a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Shawnna Rechsteiner
Original Signature of Person Authorized to Submit Application, no copies or stamps

Shawnna Rechsteiner
Print Name of Authorized Person

2/26/2020
Date

Board Use Only Date Processed:_____ Amount: 500
Check # 0400875S4

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General X Limited ____

Partnership Name: Shawnna + Joseph Rechsteiner

Mailing Address: [redacted] S. 2880 E.

City: St. George State: UT Zip Code: 84790

Telephone Number: [redacted] Fax Number: 0

Contact Person: Shawnna Rechsteiner

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
Shawnna Rechsteiner	G	50%
Joseph Rechsteiner	G	50%

List names of 4 largest partners and percentage of ownership:

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

List any physician shareholders and percentage of ownership.

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday 9 am 1 pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Shawna Rechsteiner

Responsible Person of Crimson Valley Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Shawna Rechsteiner

Original Signature of Person Authorized to Submit Application, no copies or stamps

Shawna Rechsteiner
Print Name of Authorized Person

2/26/21
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF_____)
) ss.
_____COUNTY)

I, Shawna Rechsteiner, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-charge for Crimson Valley Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Shawna Rechsteiner do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Shawna Rech
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
7th day of March, 2021.

NOTARY PUBLIC

DENISE SPRAGG-MITCHELL
Notary Public
State Of Utah
My Commission Expires 11-09-2024
COMMISSION NO. 715164

Utah Department of Commerce
Division of Corporations & Commercial Code
160 East 300 South, 2nd Floor, PO Box 146705
Salt Lake City, UT 84114-6705
Service Center: (801) 530-4849
Toll Free: (877) 526-3994 Utah Residents
Fax: (801) 530-6438
Web Site: http://www.commerce.utah.gov

03/06/2021
10111733-016003062021-923841

CERTIFICATE OF EXISTENCE

Registration Number:	10111733-0160
Business Name:	CRIMSON VALLEY PHARMACY, LLC
Registered Date:	September 27, 2016
Entity Type:	LLC - Domestic
Status:	Current

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

Jason Sterzer
Director
Division of Corporations and Commercial Code

Certificate of License Renewal

Your license has been renewed and this temporary Certificate of License Renewal allows you to practice. In approximately 15 to 30 working days you will receive your wallet card and wall certificate in the mail. If you do not receive it within this time, please contact DOPL immediately at (801) 530-6628 or (866) 275-3675 (toll-free in Utah only).

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

Certificate of License Renewal

Control Number: 10228906-1703-20190801

RENEWAL DATE: 08/01/2019

EXPIRATION DATE: Thu Sep 30 2021

ISSUED TO: Crimson Valley Pharmacy

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

10228906-1703	**Pharmacy - Class A**
10228906-8913	**Dispensing Controlled Substance License**

Please note that DOPL reserves the right to initiate action at any time against a licensee who did not meet the renewal/reinstatement requirements at the time this license was issued.

License Record Renewal Fee Summary

Date of Transaction:	08/01/2019 09:06
Primary License Renewal Fee:	103.00
Secondary License Renewal Fee:	78.00
Late Renewal Fee:	0.00
Total Fee:	181.00 PAID

Mar. 8. 2021 12:31PM No. 1211 P. 1

Utah State Tax Commission
TAXPAYER SERVICES DIVISION 210 N 1950 W SALT LAKE CITY UT 84134-9000 Website: tax.utah.gov

Letter Issue Date
March 8, 2021

Letter ID
L1518485664

Account Type
Customer

Account Number
14366418

SHAUNNA RECHSTEINER
CRIMSON VALLEY PHARMACY LLC
2351 S RIVER RD STE 3
SAINT GEORGE UT 84790-8749

TAXPAYER ACCESS POINT UTAH TAP tap.utah.gov

Business Name: CRIMSON VALLEY PHARMACY LLC
Federal Identification Number: XX-XXX7565
Department of Commerce Number: 101117330160

Letter of Good Standing

The Utah State Tax Commission certifies:

CRIMSON VALLEY PHARMACY LLC

has filed all required returns with the Utah State Tax Commission
and has paid all taxes due as of March 8, 2021.

This certificate expires April, 7, 2021.

What to Do
- Keep this certificate in your records.

Please Note
- All accounts can be audited at any time.

Contact Information
If you have any questions, please call Meleniy Fifita at 801-297-7692 or toll free 1-800-662-4335 ext. or send me a fax at 801-297-7699. You may also write to me at the address at the top of this notice.

Respectfully,
Meleniy Fifita

Taxpayer Services Division

The Utah Taxpayer Bill of Rights (Pub 2) is available on the Tax Commission's website tax.utah.gov or upon request. This publication describes your rights and obligations and the Tax Commission's procedures for appeals, refund claims and collections.
If you need an accommodation under the Americans with Disabilities Act, contact the Tax Commission at 801-297-3811 or TDD 801-297-2020. Please allow three working days for a response.

Darlene Nases

From: Shaunna Rechsteiner <crimsonvalleyrx@gmail.com>
Sent: Monday, June 7, 2021 12:54 PM
To: Darlene Nases
Subject: Re: Pharmacy Application - Crimson Valley Pharmacy, LLC - Need more information
Attachments: Organizational chart.docx

Darlene,
Officers/Directors: Joe Rechsteiner, Shaunna Rechsteiner
I have also attached the organizational chart.

On Fri, Jun 4, 2021 at 9:05 AM Darlene Nases <dnases@pharmacy.nv.gov> wrote:

Hello Shaunna,

One more thing. Can I please have a list of your officers and directors?

Regards,

Darlene Nases

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

--

Shaunna Rechsteiner, Owner, Pharmacist

Crimson Valley Pharmacy

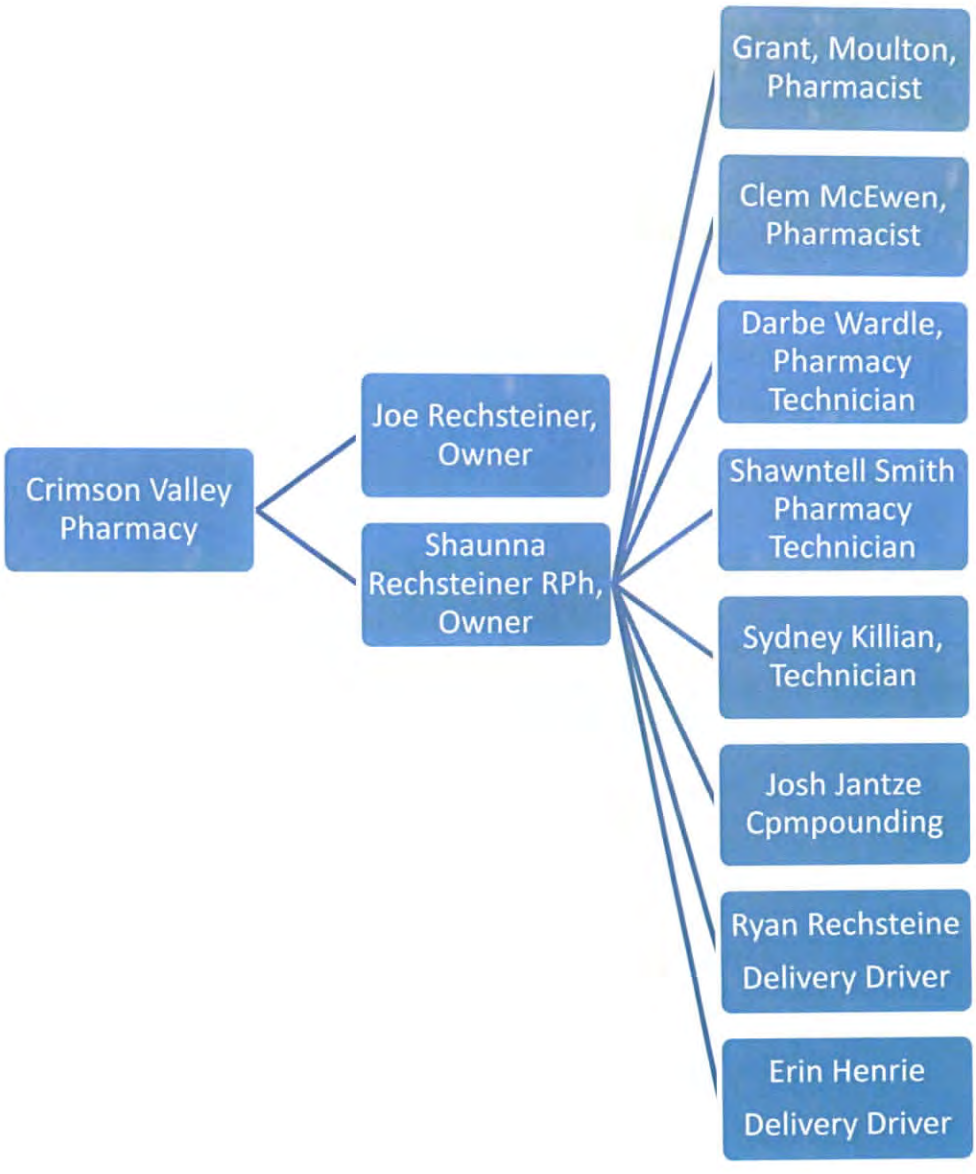
2351 S River Road Ste 3

St.George, UT 84790

435-218-7744

E-MAIL CONFIDENTIALITY NOTICE:

This e-mail, including any attachments may contain material protected and governed by the Health Insurance and Portability and Accountability Act (HIPAA). This e-mail and any files transmitted with it are confidential and are intended solely for the use or the individual or entity to which they are addressed. The authorized recipient of this


Crimson Valley Pharmacy
Joe Rechsteiner, Owner
Shaunna Rechsteiner RPh, Owner
Grant, Moulton, Pharmacist
Clem McEwen, Pharmacist
Darbe Wardle, Pharmacy Technician
Shawntell Smith Pharmacy Technician
Sydney Killian, Technician
Josh Jantze Cpmpounding
Ryan Rechsteine Delivery Driver
Erin Henrie Delivery Driver

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☐ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☑ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Sai Apothecary LLC DBA Excel Pharmacy

Physical Address: 505 Salt Lick Road, Saint Peters, MO 63376

Mailing Address: 505 Salt Lick Road,

City: Saint Peters State: MO Zip Code: 63376

Telephone: 636-278-6561 Fax: 636-278-4754

Toll Free Number: 844-626-0447 (Required per NAC 639.708)

E-mail: medshop505@gmail.com Website: www.excel-rx.com

Managing Pharmacist: Keta Jhala License Number: 20130226225

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☑	☐ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

_____
Original Signature of Person Authorized to Submit Application, no copies or stamps

Keta Shala
Print Name of Authorized Person

1/20/2021
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Keta Jhala

Business Name: Sai Apothecary LLC DBA Excel Pharmacy

Current Business Address: 505 Salt Lick Road

City: Saint Peters State: MO Zip Code: 63376

Telephone: 636-278-6561 Fax: 636-278-4754

List any physician shareholders and percentage of ownership.

Name: NONE - %: -

Name: %:

Name: %:

Name: %:

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday ____ am ____ pm

Sunday ____ am ____ pm 24 Hours ____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: -

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Keta Jhala

Responsible Person of Excel Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Keta Jhala
Print Name of Authorized Person

1/20/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF MO)
St. Charles) ss.
COUNTY.)

I, Keta Shala, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the owner for Excel Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Keta Shala, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
9 day of April, 2020.

NOTARY PUBLIC

BROOKE ELIZBETH BILL
Notary Public - Notary Seal
STATE OF MISSOURI
St. Charles County
My Commission Expires: Jan. 15, 2022
Commission # 18030913

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, JOHN R. ASHCROFT, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Sai Apothecary LLC
LC001573615

was created under the laws of this State on the 25th day of January, 2018, and is active, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 2nd day of March, 2020.

Secretary of State

Certification Number: CERT-03022020-0080

State of Missouri

Division of Professional Registration

Pharmacy
Class A, D

VALID THROUGH OCTOBER 31, 2021
ORIGINAL CERTIFICATE/LICENSE NO. 2018005661
SAI APOTHECARY LLC
EXCEL PHARMACY
HALLIE R MCCLURE, PIC
505 SALT LICK RD
SAINT PETERS MO 63376
USA

SAI APOTHECARY LLC
EXCEL PHARMACY
HALLIE R MCCLURE, PIC
505 SALT LICK RD
SAINT PETERS MO 63376
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, D

VALID THROUGH OCTOBER 31, 2021
ORIGINAL CERTIFICATE/LICENSE NO. 2018005661
Hallie R McClure - 2018024631
SAI APOTHECARY LLC
EXCEL PHARMACY
HALLIE R MCCLURE, PIC
505 SALT LICK RD
SAINT PETERS MO 63376
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

LIST OF OFFICERS/DIRECTORS

APPLICANTS BUSINESS OWNERSHIP – 100%
LEVEL OF OWNERSHIP – SOLE OWNER

OFFICER/DIRECTOR: KETA JHALA
[redacted] STURBRIDGE DRIVE, SAINT CHARLES, MO 63376
[redacted]

Michael L. Parson
Governor
State of Missouri

Sarah Ledgerwood, Interim Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

This is to certify that the records of the Missouri Division of Professional Registration indicate the following information regarding SAI Apothecary LLC.

LICENSE TYPE:	Pharmacy
LICENSE NUMBER:	2018005551
ADDRESS:	Keta R Jhala, PIC 505 Salt Lick Rd Saint Peters, MO 63376
DATE ISSUED:	2/15/2018
STATUS:	Active
EXPIRATION DATE:	10/31/2021
DISCIPLINARY ACTION:	None

Laura Henke
Missouri Board of Pharmacy

6.5.2020
Date

This is the only form that will be used by the Missouri Board of Pharmacy for the purpose of license verification.

The Division and its boards will begin to accept members of the public. Rather than entering the building individuals may continue to conduct business by contacting the boards via phone and/or email as listed on the left below under General Inquiries on each individual board website (boards.asp), at the bottom of this page under "Contact Us" or drop items in our drop box (we ask that all items be placed in a sealed envelope labeled with the board name).

Board of Pharmacy

PR Home (https://pr.mo.gov/) » Pharmacy Home (https://pr.mo.gov/pharmacists.asp) » Pharmacy Licensee Search (https://pr.mo.gov/pharmacy-licensee-search.asp)

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	SAI Apothecary LLC
Profession Name:	Pharmacy
Licensee Number:	2018005551
Expiration Date:	10/31/2021
Original Issue Date:	2/15/2018
Address:	Keta R Jhala, PIC
Address Con't:	505 Salt Lick Rd
City, State Zip:	Saint Peters, MO 63376
County:	St. Charles
Practitioner DBA Name:	Excel Pharmacy
Classification:	Class A, D, J

Current Discipline Status:	None

Board of Pharmacy (https://pr.mo.gov/pharmacists)
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY

800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov (mailto:MissouriBOP@pr.mo.gov)
https://pr.mo.gov/pharmacists (https://pr.mo.gov/pharmacists)

LC001573615
Date Filed: 1/25/2018
John R. Ashcroft
Missouri Secretary of State

State of Missouri
John R. Ashcroft, Secretary of State
Corporations Division
PO Box 778 / 600 W. Main St., Rm. 322
Jefferson City, MO 65102

Articles of Organization

(Submit with filing fee of $105.00)

1. The name of the limited liability company is
Sai Apothecary LLC
(Must include "Limited Liability Company," "Limited Company," "LC," "L.C.," "L.L.C.," or "LLC")

2. The purpose(s) for which the limited liability company is organized:
The purpose of the limited liability company is to operate a sustainable apothecary in the community and surrounding areas.

3. The name and address of the limited liability company's registered agent in Missouri is:

Name	*Street Address: May not use PO Box unless street address also provided*	*City/State/Zip*
MISSOURI BUSINESS SERVICES, INC.	9666 Olive Boulevard, Suite 690	Saint Louis MO 63132

4. The management of the limited liability company is vested in: ☐ managers ☒ members *(check one)*

5. The events, if any, on which the limited liability company is to dissolve or the number of years the limited liability company is to continue, which may be any number or perpetual: Perpetual
(The answer to this question could cause possible tax consequences, you may wish to consult with your attorney or accountant)

6. The name(s) and street address(es) of each organizer *(PO box may only be used in addition to a physical street address)*:
(Organizer(s) are not required to be member(s), manager(s) or owner(s)

Name	*Address*	*City/State/Zip*
Jhala, Keta	505 Salt Lick Rd	St Peters MO 63376

7. ☐ Series LLC (OPTIONAL) Pursuant to Section 347.186, the limited liability company may establish a designated series in its operating agreement. The names of the series must include the full name of the limited liability company and are the following:

New Series:
☐ The limited liability company gives notice that the series has limited liability.

New Series:
☐ The limited liability company gives notice that the series has limited liability.

New Series:
☐ The limited liability company gives notice that the series has limited liability.

(Each separate series must also file an Attachment Form LLC 1A.)

Name and address to return filed document:
Name: Laphilia Davis
Address: Email: butlerdavisaccounting@gmail.com
City, State, and Zip Code:

8. The effective date of this document is the date it is filed by the Secretary of State of Missouri unless a future date is otherwise indicated: _____

(Date may not be more than 90 days after the filing date in this office)

In Affirmation thereof, the facts stated above are true and correct:
(The undersigned understands that false statements made in this filing are subject to the penalties provided under Section 575.040, RSMo)
All organizers must sign:

Keta Jhala	KETA JHALA	01/25/2018
Organizer Signature	*Printed Name*	*Date of Signature*

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CERTIFICATE OF ORGANIZATION

WHEREAS,

Sai Apothecary LLC
LC001573615

filed its Articles of Organization with this office on the 25th day of January, 2018, and that filing was found to conform to the Missouri Limited Liability Company Act.

NOW, THEREFORE, I, John R. Ashcroft, Secretary of State of the State of Missouri, do by virtue of the authority vested in me by law, do certify and declare that on the 25th day of January, 2018, the above entity is a Limited Liability Company, organized in this state and entitled to any rights granted to Limited Liability Companies.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 25th day of January, 2018.

Secretary of State

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CERTIFICATE OF GOOD STANDING

I, John R. Ashcroft, Secretary of State of the STATE OF MISSOURI, do hereby certify that the records in my office and in my care and custody reveal that

Sai Apothecary LLC

LC001573615

A Missouri entity was created under the laws of this State on 1/25/2018, and is Active, having fully complied with all the requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, the 1st day of June, 2021.

Secretary of State

Certification Number: CERT-IN85875

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: MedQuickRx

Physical Address: 5757 Wilshire Blvd., Suite 320, Los Angeles CA 90036

Mailing Address: 5757 Wilshire Blvd., Suite 320, Los Angeles CA 90036

City: Los Angeles State: CA Zip Code: 90036

Telephone: 310.935.1899 Fax: 310.691.1731

Toll Free Number: 877.421.3405 (Required per NAC 639.708)

E-mail: eFAX@MedQuickRx.com Website: MedQuickRx.com

Managing Pharmacist: Priscilla Eusebio License Number: RPH 36023 ✓

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☑ ☐	Retail	☐ ☑	Off-site Cognitive Services
☐ ☑	Hospital (# beds_____)	☐ ☑	Parenteral **
☑ ☐	Internet	☑	Parenteral (outpatient)
☐ ☑	Nuclear	☐ ☑	Outpatient/Discharge
☐ ☑	Ambulatory Surgery Center	☐ ☑	Mail Service
☐ ☑	Community	☐ ☑	Long Term Care
☐ ☑	Other: _____	☐ ☑	Sterile Compounding **
		☑ ☐	Non Sterile Compounding
	All boxes must be checked	☐ ☑	Mail Service Sterile Compounding **
	For the application to be complete	☐ ☑	Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Poch Blanco
Print Name of Authorized Person

10-21-2020
Date

Board Use Only Date Processed:_____ Amount: 500
mo # 2707650727 7

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: CA

Parent Company if any: N/A

Mailing Address: 5757 Wilshire Blvd., Suite 320

City: Los Angeles State: CA Zip: 90036

Telephone: 310.935.1899 Fax: 310.691.1731

Contact Person: Poch Blanco

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Poch Blanco [redacted] W 1st St., Suite [redacted] Los Angeles CA 90012
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? 1000

4) What date did the corporation actually receive the cash assets? 1/12/2017

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 6 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Poch Blanco

Responsible Person of MedQuickRx

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Poch Blanco
Print Name of Authorized Person

10-21-2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF CALIFORNIA)
) ss.
LOS ANGELES COUNTY)

I, Poch Blanco, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO for MedQuickRx (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Poch Blanco, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
21 day of OCTOBER, 2020.

NOTARY PUBLIC

DON CURTIS QUIMINE
Notary Public - California
Los Angeles County
Commission # 2304657
My Comm. Expires Oct 9, 2023

Transmitting Controlled Substance Prescription Data

Pursuant to NAC 639.926, pharmacies and dispensing practitioners that dispense controlled substances listed in schedule II, III or IV are required to submit data to the Board each week; however, we highly encourage dispensers to submit data on a nightly basis when possible. If a dispenser has not dispensed any controlled substances for the required time period, the dispenser is required to submit a zero reporting transmission.

The Nevada State Board of Pharmacy contracts with Appriss to manage the data collection for the Nevada Prescription Monitoring Program (PMP). For information to register and submit data please visit: http://bop.nv.gov. Click Links, click Prescription Monitoring Program, click Dispenser Guide.

If you have any questions or need additional information, please email: pmp@pharmacy.nv.gov

APPLICATION FOR CERTIFICATION AS A PROVIDER OF INTERNET PHARMACY SERVICES

Addendum to Pharmacy Application
(Only required if providing internet services)

GENERAL INFORMATION

Name of Nevada license pharmacy: MedQuickRx

Nevada license number: Pending

Websites in use or intended to be used: MedQuickRx.com

Affiliated websites (websites that link to or otherwise direct users to your website):

VIPPS CERTIFICATION

Is the pharmacy VIPPS (Verified Internet Pharmacy Practice Sites administered be NABP) certified? Please provide a copy with application. Yes ☐ No ☑

If yes, please sign and date page 3 and you will not need to answer questions 1 through 8.

PHARMACIES LACKING VIPPS CERTIFICATION

1. Is the pharmacy licensed in each state in which the pharmacy will practice pharmacy Yes ☑ No ☐

PLEASE ATTACH A SEPARATE SHEET LISTING ALL THE STATES IN WHICH YOU ARE LICENSED, INCLUDING THE DATE OF INITIAL LICENSURE AND THE LICENSE NUMBER.

2. Does the pharmacy maintain and enforce policies and procedures that ensure the following:

A) That the pharmacy will establish the authenticity of each prescription that the pharmacy receives? Yes ☑ No ☐

B) That the pharmacy will not fill any prescription which has been previously filled by another pharmacy? Yes ☑ No ☐

C) That for each pharmacy the pharmacy fills the prescription cannot be filled by another pharmacy? Yes ☑ No ☐

D) That the pharmacy will authenticate the identity of each patient and prescribing practitioner? Yes ☑ No ☐

E) That the prescriptions will be filled in compliance with all applicable federal and state laws? Yes ☑ No ☐

F) That a patient or the caregiver of the patient may make a complaint to the pharmacy regarding a prescription? Yes ☑ No ☐

G) That if a complaint is made, the complaint will be investigated thoroughly and that the results of the investigation will be communicated to the patient or caregiver? Yes ☑ No ☐

H) That if the investigation of a complaint reveals that the operations of the pharmacy resulted in an error in the processing or filling of the prescription, appropriate remedial action was taken by the pharmacy? Yes ☑ No ☐

I) That the pharmacy will communicate to a patient or a prescribing practitioner any delay that might jeopardize or alter the drug therapy of the patient with respect to delivering the prescribed drug or device? Yes ☑ No ☐

J) That the pharmacy will communicate to a patient information regarding recalls of drugs and the appropriate means to dispose of expired, damaged or unusable drugs or devices? Yes ☑ No ☐

3. Does the pharmacy obtain and maintain patient information necessary to facilitate review of drug utilization and counseling of patients pursuant to any applicable statutes? Yes ☑ No ☐

4. Will the pharmacy provide review of drug utilization and counseling of patients pursuant to the applicable statutes in the state in which the patient resides? Yes ☑ No ☐

5. Does the pharmacy maintain controls of its computer system, information concerning patients, and other such confidential information and documents to prevent unauthorized or unlawful access to all such confidential information and documents? Yes ☑ No ☐

6. Does the pharmacy comply with applicable federal and state laws regarding the following:

   A) To the dispensing of prescription drugs? Yes ☑ No ☐

   B) To the record keeping related to the patients served by the pharmacy, the purchase of prescription drugs and the sale and dispensing of prescription drugs? Yes ☑ No ☐

   C) To the sale of over-the-counter products, including any special requirements related to products that have been identified as precursors to the manufacture or compounding of illegal drugs ? Yes ☑ No ☐

7. Does the pharmacy ship prescriptions to a patient using secure and traceable means? Yes ☑ No ☐

8. Does the pharmacy ship prescriptions to a patient using packaging or devices which will ensure that the prescription is maintained within appropriate standards pertaining to temperature, light and humidity as described in the *United States Pharmacopoeia, 25th* edition, 2002, which is hereby adopted by reference? Yes ☑ No ☐

PLEASE ATTACH A COPY OF YOUR POLICIES AND PROCEDURES.

The signature below certifies that the answers provided in this application are true, correct and complete.

[signature] 10-21-2020

Signature of Owner Date

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 57546

NAME: MEDQUICKRX

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

5757 WILSHIRE BLVD STE 320
LOS ANGELES CA 90036
LOS ANGELES COUNTY

ISSUANCE DATE

FEBRUARY 5, 2020

EXPIRATION DATE

FEBRUARY 1, 2022

CURRENT DATE / TIME

APRIL 14, 2021
2:45:39 PM

LICENSE RELATIONSHIPS

NAME: EUSEBIO, PRISCILLA REYES

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 36023 **PRIMARY STATUS:** CLEAR

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO PHY 57548

ISSUE DATE FEBRUARY 05, 2020

MEDQUICKRX

5757 WILSHIRE BLVD STE 320
LOS ANGELES CA 90036

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
PRISCILLA REYES EUSEBIO

PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL FEBRUARY 01, 2021

RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100

Maria Herrera

From: Joe Matkowsky <JMatkowsky@LicenseLogix.com>
Sent: Tuesday, June 1, 2021 4:58 PM
To: Maria Herrera
Subject: RE: Nevada Out-of-State Application- MedQuickRx

Follow Up Flag: Follow up
Flag Status: Completed

Hello Maria,

Care Prescription Management Inc. is the name of the entity as filed with the CA secretary of state. They are doing business as MedQuickRx. Do you need to see any additional paperwork linking the names?

There is only one officer and director for this entity: Poch Blanco. Please let me know if you need any additional info on him to proceed. Thanks!

Best,
Joe

If you have a few minutes, please share your LicenseLogix experience!
Click Here

• • •

licenselogix

Joe Matkowsky | Account Manager, Team Oak
jmatkowsky@licenselogix.com | www.licenselogix.com

140 Grand St, Suite 300 | White Plains, NY 10601
Office: 800-292-0909 x 440 | Fax: 212.672.1105

Questions/Feedback? Please contact my manager, Shayna Desai, at sdesai@licenselogix.com!

Please note, my business hours are Monday – Friday 9:00 am to 6:00 pm Pacific Time

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, June 1, 2021 8:46 AM
To: License Logix (Service) <Service@licenselogix.com>
Subject: Nevada Out-of-State Application- MedQuickRx

We are in receipt of your Out-of-State application for a pharmacy license. We are missing the documents below, the application can't be placed on an agenda for approval until receipt of all required documents.

- The Certificate of Good Standing from your secretary of state is listed under Care Prescription Management Inc.? Please verify if they are the parent company of MedQuickRx?
- List of Officers and Directors

All items must be received to move forward with processing your application.

If you have any questions, please feel free to contact us.

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
775-850-1440
m.herrera@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	CARE PRESCRIPTION MANAGEMENT INC
File Number:	C3982074
Registration Date:	01/12/2017
Entity Type:	DOMESTIC STOCK CORPORATION
Jurisdiction:	CALIFORNIA
Status:	ACTIVE (GOOD STANDING)

As of April 15, 2021 (Certification Date), the entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 16, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: Y645NVR

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at bebizfile.sos.ca.gov/certification/index.

MedQuickRx License List

CA

2/2/2020 PHY 57546

AZ

10/19/20 Y008510

OH

3/4/21 0242000260

WA

1/10/21 PHNR.FO61136057

4S

This matter was continued to a future Board Meeting.

4T

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☒ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: CARE AIRWAYS CORP

Physical Address: 1095 BROKEN SOUND PKWY NW SUITE 101
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: same

City BOCA RATON State: FL Zip Code: 33487

Telephone: 561. 221. 9264 Fax: 561. 634. 3424

E-mail: martin@careairways.com Website: under construction

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8am to 5pm Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5 Sat: CLOSED Sun: CLOSED Holidays: to ON CALL

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: CRAIG MARTIN OTTO

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☒ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: CRAIG MARTIN OTTO Telephone: 855. 713. 1012

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

pending _____ _____ _____

_____ _____ _____

_____ _____ _____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: n/a
- Advanced Practitioner of Nursing Name: n/a
- Physician's Assistant Name: n/a
- Physical Therapist Name: n/a
- Occupational Therapist Name: n/a
- Registered Nurse Name: n/a
- Respiratory Therapist Name: n/a

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

CRAIG MARTIN OTTO

Print Name of Authorized Person

5/13/21

Date

Board Use Only	Received:_____	Amount: 500 check # 105

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: FLORIDA

Parent Company if any: N/A

Corporation Name: CARE AIRWAYS CORP

Mailing Address: 1095 BROKEN SOUND PKWY NW SUITE 101

City: BOCA RATON State: FL Zip: 33487

Telephone: 855.713.1012 Fax: 561.634 3424

Contact Person: CRAIG MARTIN OTTO

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) CORY LUCKNER 1095 BROKEN SOUND PKWY NW BOCA RATON, FL 3348]
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? +/-

4) What date did the corporation actually receive the cash assets? 12/10/20

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

CORY LUCKNER (OWNER)
CRAIG MARTIN OTTO (DIRECTOR)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/8/2021

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

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

PRODUCER: VGM Insurance Services, Inc. 1111 W. San Marnan Dr. Waterloo IA 50701	CONTACT NAME: Ashley Haynes PHONE (A/C, No, Ext): (844) 346-3937 FAX (A/C, No): E-MAIL ADDRESS: Ashley.Haynes@vgm.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: BENCHMARK INSURANCE COMPANY — 41394
INSURED: Care Airways Corp 1095 Broken Sound Parkway NW Suite 101 Boca Raton FL 33487	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			D1020 G6482-1	03/1/2021	03/1/2022	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 1,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 1,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	$
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$

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

Location: 1095 Broken Sound Parkway NW Suite 101, Boca Raton FL 33487

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2014 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

State of Florida
Department of State

I certify from the records of this office that CARE AIRWAYS CORP. is a corporation organized under the laws of the State of Florida, filed on December 10, 2020, effective December 10, 2020.

The document number of this corporation is P20000096788.

I further certify that said corporation has paid all fees due this office through December 31, 2021, that its most recent annual report/uniform business report was filed on February 16, 2021, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Sixteenth day of February, 2021



Secretary of State

Tracking Number: 8285534609CC

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

National Provider Identifier

Inbox

customerservice@npienumerator.com 1:38 PM (31 minutes ago)

to me

Original Print Date: January 19, 2021

Enumeration Date: November 17, 2020

A request for a National Provider Identifier for the following provider was recently submitted to https://nppes.cms.hhs.gov, and you were listed as the contact person. This is to inform you that the request was successfully processed and the following NPI has been assigned:1649873381.

Care Airways Corp
EIN: =====9914
Other Organization Name: Care Airways
Parent LBN: Care Airways Corp
Parent TIN: =====9914

Practice Location:
1095 Broken Sound Pkwy NW Ste 101
Boca Raton, FL 33487-3503

Provider Taxonomies:
Taxonomy: 332BX2000X
Details: Durable Medical Equipment & Medical Supplies/Oxygen Equipment & Supplies
This is the Primary Taxonomy.

If you have any questions about this notification you may contact the NPI Enumerator Monday through Friday, 9am to 5pm (Eastern Time)* at:
NPI Enumerator
PO Box 6059
Fargo, ND 58108-6059
1-800-465-3203 (NPI Toll-Free)
1-800-692-2326 (NPI TTY for the deaf, hard of hearing, or those with speech difficulties)
customerservice@npienumerator.com

*Holiday hours may vary

You may view or change this provider's NPPES information by logging onto the NPPES website at https://nppes.cms.hhs.gov.

Please note: If you are not the provider, you are required to inform the provider of the information in this e-mail and furnish a copy of this notification to the provider.

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 12-10-2020

Employer Identification Number:
85-4229914

Form: SS-4

Number of this notice: CP 575 A

CARE AIRWAYS CORP
% CORY LUCKNER
1095 BROKEN SOUND PKWY NW STE 101
BOCA RATON, FL 33487

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 85-4229914. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear off stub and return it to us.

Based on the information received from you or your representative, you must file the following form(s) by the date(s) shown.

Form 1120 04/15/2021

If you have questions about the form(s) or the due date(s) shown, you can call us at the phone number or write to us at the address shown at the top of this notice. If you need help in determining your annual accounting period (tax year), see Publication 538, *Accounting Periods and Methods*.

We assigned you a tax classification based on information obtained from you or your representative. It is not a legal determination of your tax classification, and is not binding on the IRS. If you want a legal determination of your tax classification, you may request a private letter ruling from the IRS under the guidelines in Revenue Procedure 2004-1, 2004-1 I.R.B. 1 (or superseding Revenue Procedure for the year at issue). Note: Certain tax classification elections can be requested by filing Form 8832, *Entity Classification Election*. See Form 8832 and its instructions for additional information.

IMPORTANT INFORMATION FOR S CORPORATION ELECTION:

If you intend to elect to file your return as a small business corporation, an election to file a Form 1120-S must be made within certain timeframes and the corporation must meet certain tests. All of this information is included in the instructions for Form 2553, *Election by a Small Business Corporation*.

(IRS USE ONLY) 575A 12-10-2020 CARE B 9999999999 SS-4

If you are required to deposit for employment taxes (Forms 941, 943, 940, 944, 945, CT-1, or 1042), excise taxes (Form 720), or income taxes (Form 1120), you will receive a Welcome Package shortly, which includes instructions for making your deposits electronically through the Electronic Federal Tax Payment System (EFTPS). A Personal Identification Number (PIN) for EFTPS will also be sent to you under separate cover. Please activate the PIN once you receive it, even if you have requested the services of a tax professional or representative. For more information about EFTPS, refer to Publication 966, *Electronic Choices to Pay All Your Federal Taxes.* If you need to make a deposit immediately, you will need to make arrangements with your Financial Institution to complete a wire transfer.

The IRS is committed to helping all taxpayers comply with their tax filing obligations. If you need help completing your returns or meeting your tax obligations, Authorized e-file Providers, such as Reporting Agents (payroll service providers) are available to assist you. Visit the IRS Web site at www.irs.gov for a list of companies that offer IRS e-file for business products and services. The list provides addresses, telephone numbers, and links to their Web sites.

To obtain tax forms and publications, including those referenced in this notice, visit our Web site at www.irs.gov. If you do not have access to the Internet, call 1-800-829-3676 (TTY/TDD 1-800-829-4059) or visit your local IRS office.

IMPORTANT REMINDERS:

* Keep a copy of this notice in your permanent records. **This notice is issued only one time and the IRS will not be able to generate a duplicate copy for you.** You may give a copy of this document to anyone asking for proof of your EIN.

* Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.

* Refer to this EIN on your tax-related correspondence and documents.

If you have questions about your EIN, you can call us at the phone number or write to us at the address shown at the top of this notice. If you write, please tear off the stub at the bottom of this notice and send it along with your letter. If you do not need to write us, do not complete and return the stub.

Your name control associated with this EIN is CARE. You will need to provide this information, along with your EIN, if you file your returns electronically.

Thank you for your cooperation.

Sunbiz.org DIVISION of CORPORATIONS an official State of Florida website

Detail by Entity Name

Florida Profit Corporation
CARE AIRWAYS CORP.

Filing Information

Document Number	P20000096788
FEI/EIN Number	85-4229914
Date Filed	12/10/2020
Effective Date	12/10/2020
State	FL
Status	ACTIVE

Principal Address

1095 BROKEN SOUND PKWY. NW
101
BOCA RATON, FL 33487

Mailing Address

1095 BROKEN SOUND PKWY. NW
101
BOCA RATON, FL 33487

Registered Agent Name & Address

LUCKNER, CORY T
1095 BROKEN SOUND PKWY. NW.
101
BOCA RATON, FL 33487

Officer/Director Detail

Name & Address

Title P

LUCKNER, CORY T
1095 BROKEN SOUND PKWY. NW
BOCA RATON, FL 33487

Title Director

Otto, Craig Martin
1095 BROKEN SOUND PKWY. NW
101
BOCA RATON, FL 33487

Annual Reports

Report Year	Filed Date
2021	02/16/2021

Document Images

02/16/2021 -- ANNUAL REPORT	View image in PDF format
12/10/2020 -- Domestic Profit	View image in PDF format

Florida Department of State, Division of Corporations

View current license information at: Floridahealthfinder.gov

LICENSE #: 1314915
CERTIFICATE #: 24289

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

Home Medical Equipment Provider

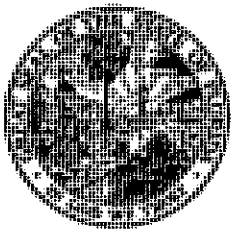
LICENSED

This is to confirm that CARE AIRWAYS CORP has complied with rules and regulations adopted by the State of Florida, Agency for Health Care Administration, as authorized in Chapter 400, Part VII and Chapter 408, Part II, Florida Statutes, and Chapter 59A-25, Florida Administrative Code, and is authorized to operate the following:

CARE AIRWAYS CORP
1095 Broken Sound Pkwy Nw
Ste 101
Boca Raton, FL 33487
in the following counties:
ALL COUNTIES

EFFECTIVE DATE: 05/11/2021

EXPIRATION DATE: 05/10/2023



Simone Marstiller, Secretary
Agency for Health Care Administration

CERTIFICATE *of* ACCREDITATION

ACCREDITATION COMMISSION FOR HEALTH CARE CERTIFIES THAT:

CareAirways

BOCA RATON, FLORIDA

HAS DEMONSTRATED A COMMITMENT TO PROVIDING QUALITY CARE AND SERVICES TO CONSUMERS THROUGH COMPLIANCE WITH ACHC'S NATIONALLY RECOGNIZED STANDARDS FOR ACCREDITATION AND IS THEREFORE GRANTED ACCREDITATION FOR THE FOLLOWING:

DMEPOS

Home/Durable Medical Equipment Services

FROM *January 21, 2021* THROUGH *January 20, 2024*

PRESIDENT & CHIEF EXECUTIVE OFFICER

CHAIRMAN OF THE BOARD OF COMMISSIONERS

ACCREDITATION COMMISSION FOR HEALTH CARE ACHC

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

Office of Respiratory Therapy Licensure

Carla Rae Fetzer
Respiratory Therapist

RTL.0004342 ★ 09/01/2020
Number Issue Date
Active 08/31/2022
Credential Status ★Expire Date

Verify this credential at: dpo.colorado.gov

★ 1876 ★

Division Director Ronne Hines Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

Office of Respiratory Therapy Licensure

Carla Rae Fetzer
Respiratory Therapist

RTL.0004342 ★ 09/01/2020
Number Issue Date
Active 08/31/2022
Credential Status ★Expire Date

Verify this credential at: dpo.colorado.gov

★ 1876 ★

Division Director Ronne Hines Credential Holder Signature

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 5/20/21

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for HOME MEDICAL EQUIPMENT (DIRECTOR)
Nature of MDEG

CARE AIRWAYS CORP
Name and Address of Business for Which MDEG Administrator Is Requested

1095 BEORENSOUND PKWY NW SUITE 101 BOCA RATON, FL 33487
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

OTTO (Last Name) CRAIG (First Name) MARTIN (Middle Name)

MARTIN
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] GOSHER WAY (Present Residence Address-Street or RFD) BOCA RATON (City) FL 33428 (State/Zip)

1095 BROKEN SOUND PKWY (Present Business Address) Dates 12/10/20 BOCA RATON (City) FL 33487 (State/Zip)

DIRECTOR (Present Position with the MDEG) Dates 11/17/20 TO PRESENT

Phone: 855.713.1012 Fax: 561 634 3424

Email address: martin@careairways.com

[redacted] (Date of Birth) PERTH AMBOY, NJ MONMOUTH COUNTY (Place of Birth (City, County, State))

56 (Age) [redacted] (Social Security Number or ITIN) M (Sex)

BRO (Color of Eyes) BRO (Color of Hair) 150 (Weight) 5'8" (Height)

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No

If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

PLEASE SEE ATTACHED RESUME

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

I have ~~I have not~~ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ~~I have not~~ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ~~I have not~~ been the subject of an administrative action whether completed or pending.
3. I have ~~I have not~~ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

a) Board Administrative Action: State: _____
b) Date: _____
Case Number: _____

c) Criminal Action: State: _____
Date: _____
Case Number: _____
County: _____
Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG? ~~Yes~~ No

5 .Will you be employed fulltime with the MDEG? ~~Yes~~ No

6 .Will you be present at the site of the MDEG during its normal operating hours? ~~Yes~~ No

If you answer No to questions 4, 5 or 6 please provide a written letter of explanation.

.....

.....

.....

.....

.....



Date of photograph 5/20/21

I, CRAIG MARTIN OTTO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

Original Signature of Applicant

CRAIG MARTIN OTTO

Boca Raton, FL 33428 ♦ H: [redacted] ♦ C: [redacted] ♦ [redacted]

PROFESSIONAL SUMMARY

Entrepreneurial Sales Professional with excellent business acumen and proven history of driving technical sales, market share and revenue growth. Super strong work ethic with natural ability to build key relationships through communication, customer service, listening and negotiation skills. Successfully leads and motivates teams to execute business opportunities and close sales in fast-paced environments with tight deadlines.

SKILLS

- Business Development
- Rapport Building
- Business Management and Development
- Market Research
- Budgeting
- Strategic Development
- Product Sales and Sales Goals
- Marketing
- Presentation Skills
- Product development
- Team Leadership and Alignment
- Product Development and Launchs
- Business Operations
- Expert Phone and Face to Face Sales Skills

WORK HISTORY

Small business owner, 05/2015 to 04/2020

US Oxygen Sales LLC – Boca Raton, FL

- Direct to consumer Medical Sales specializing in portable oxygen concentrators.
- Generated $ 3 Million in annual revenue year over year from Zero.
- Oversaw business budget planning and administration, accounting functions, purchasing and bi-weekly payroll to handle financial needs, with intense focus on SEO and Internet Sales and Marketing.

Sr. Global Product Manager, 01/2011 to 05/2015

Philips Healthcare, Home Respiratory Care – Pittsburgh, PA

- Focus on Hospital to Home Product solutions focused on Patient Outcomes.
- Successfully developed and launched innovative new home oxygen concentrator.
- Conceptualized and deployed enhanced product features and optimized implementation for use in marketing strategies.
- Liaised with clients to develop deep understanding of business needs and current market landscape.
- Consulted with product development teams to enhance products based on customer data.
- Documented user stories (Focus Groups), specifications and product features into detailed work order to communicate across teams and mandatory build requirements.
- Collaborated with sales, marketing and support teams to launch products on time and within budget.

Director Business Development/President, 01/2006 to 01/2011
MRB Acquisition Corporation – Fort Lauderdale, FL

- Founder of Direct to Consumer Home Oxygen Business Model.
- US Direct to consumer provider of portable oxygen concentrators and medical devices.
- Grew to #1 Provider of Portable Oxygen Concentrators based on CMS/Medicare Billing Data.
- Coordinated innovative strategies to accomplish objectives and boost long-term profitability.
- Identified and pursued valuable business opportunities to generate new company revenue and improve bottom line profit.
- Established, initiated and optimized business development strategies based on company targets, product specifications, market data and budget factors.

Outside Sales/Executive Consultant/Business Development, 01/2003 to 01/2006
Lincare, Inc – Clearwater, FL

- US Market leading provider of Home Respiratory Solutions.
- Rapidly turned around P/L in underperforming Northeast Region.
- Created Early Intervention programs that helped Lincare outperform its competitors.
- Researched potential clients and markets to prepare for appointments.
- Updated sales strategies and marketing channels to increase overall profitability by 150 %.
- Used consultative sales approach to understand and meet customer needs.

V.P, International Sales and Operations, 01/1992 to 01/2002
Pride Mobility Products, Inc – Exeter, Pa

- Designers and Manufacturers of Consumer & Rehabilitation products.
- Global Business Development, Sales, Operations & Distribution.
- Reported directly to Chairman & CEO.
- Established Subsidiaries in the UK, Netherlands, Italy, Australia, and Canada.
- Developed new and modified existing products to fit country specific market requirements.
- Managed OEM manufacturing operations in Taiwan, China & Korea.
- Annual export growth more than 100% over several successive years.
- Recipient of State of PA Governors Award (Tom Ridge) for Export Excellence (1999).
- Increased revenue from zero to $100 M over 10 years, responsible for 20% of company's overall annual Revenue.

Key Physician/Key Product Specialist, 01/1990 to 01/1991
Glaxo SmithKline Pharmaceuticals – Philadelphia, Pa

EDUCATION

1987-1990
PCPM Temple School of Medicine - Philadelphia, PA

B.S: Biology/Chemistry, 1986
University of Scranton-Scranton, PA

4U

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5
☒ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: MDC Homecare LLC dba CRT

Physical Address: 8840 Orchard Tree Lane Towson MD 21286
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 40 BNA drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3230 Fax: none

E-mail: hbeasley@mdc-inc.com Website: www.wellmed.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 730 to 430 Tue: 7:30 to 430 Wed: 7:30 to 430 Thu: 730 to 430 Fri: 7:30 to 430 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Courtney Barrett

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

none _____ _____ _____

We only drop ship to patients no other contact

_____ _____ _____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley

Print Name of Authorized Person

1/20/2021

Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: NDC Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Beasley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
NDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: See above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: Medmarc Casualty Insurance Company — 22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

COVERAGES **CERTIFICATE NUMBER: W18797041** **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? ☐ N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

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

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Page 1 of 1

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General _____ Interpreter _____ Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant **Mark Tyler Seitz** pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years 11 Months 29 Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months 0 Days 3 Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years 11 Months 29 Days

$350.00 Fine

Special Conditions :

I hereby certify that this is a true and exact copy of the original

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton III Div 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

Authentication: 202460786

Date: 02-08-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

4V

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5
☒ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: Curitec, LLC

Physical Address: 421 Canal St, Ste 201, New Smyrna Beach, FL 32168
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 421 Canal St, Ste 201

City: New Smyrna Beach State: FL Zip Code: 32168

Telephone: 888-878-8034 Fax: 386-643-1234

E-mail: support@curitec.com Website: curitec.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9am to 5pm Tue: 9am to 5pm Wed: 9am to 5pm Thu: 9am to 5pm Fri: 9am to 5pm Sat: closed to Sun: closed to Holidays: closed to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Maria Percival

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: Surgical Dressings

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

PTAN: 7718580001

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: n/a
- Advanced Practitioner of Nursing Name: n/a
- Physician's Assistant Name: n/a
- Physical Therapist Name: n/a
- Occupational Therapist Name: n/a
- Registered Nurse Name: n/a
- Respiratory Therapist Name: n/a

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Nicholas Percival
Print Name of Authorized Person

MAY 17, 2021
Date

Board Use Only	Received:	Amount: 500 Check # 9204

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited x

Partnership Name: Curitec, LLC

Mailing Address: 421 Canal St, Ste 201

City: New Smyrna Beach State: FL Zip: 32168

Telephone: 888-878-8034 Fax: 386-643-1234

Contact Person: Stacey Thomas

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
Maria Percival	L	50
Nicholas Percival	L	50

List names of 4 largest partners and percentage of ownership:

Name: Maria Percival %: 50

Name: Nicholas Percival %: 50

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 10/12/2020

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

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

PRODUCER	CONTACT NAME:	
J W Edens Insurance 109 Magnolia Street New Smyrna Beach, FL 32168	PHONE (A/C, No, Ext): 386-428-6448	FAX (A/C, No): 386-427-7811
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Lloyds	
INSURED Curitec LLC 421 Canal St. Ste 201 New Smyrna Beach, FL 32168	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

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

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	GENERAL LIABILITY ☑ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☑ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ☑ POLICY ☐ PRO-JECT ☐ LOC			PGIARK1004900	10/15/20	10/15/21	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 3,000,000
							PRODUCTS - COMP/OP AGG	$ 3,000,000
								$
	AUTOMOBILE LIABILITY ☐ ANY AUTO ☐ ALL OWNED AUTOS ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ☐ NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR ☐ EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ☐ RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N ☐ N/A If yes, describe under DESCRIPTION OF OPERATIONS below						WC STATU-TORY LIMITS ☐ OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Professional Liability			PGIARK1004900	10/15/20	10/15/21	1,000,000 each claim 3,000,000 aggregate	

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

CERTIFICATE HOLDER

National Supplier Clearinghouse
Post Office Box 100142
Columbia, SC 29202-3142

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Wayne Edens

© 1988-2010 ACORD CORPORATION. All rights reserved.

State of Florida
Department of State

I certify from the records of this office that CURITEC, LLC is a limited liability company organized under the laws of the State of Florida, filed on October 4, 2018.

The document number of this limited liability company is L18000235084.

I further certify that said limited liability company has paid all fees due this office through December 31, 2020, that its most recent annual report was filed on April 8, 2020, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-sixth day of May, 2021



Secretary of State

Tracking Number: 6994957647CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

CURITEC

List of Curitec LLC. Directors and Officers:

Maria Percival: CEO / Administrator

Nick Percival: COO / Director

421 Canal Street Suite 201, New Smyrna Beach, Florida 32168
Phone: 832-662-HEAL (4325) Fax: 386-643-1234
WWW.CURITEC.COM

CURITEC

To: Nevada Board of Pharmacy,

Re: Explanation of why Our MDEG Administrator is not always present at our Curitec site.

CURITEC, LLC. is an accredited Medicare Part B supplier of durable medical supplies, namely advanced wound care supplies and surgical dressings to skilled nursing and hospice facilities. The wound care supplies are ordered by staff at these facilities, either in-person or by phone, and the products are then shipped directly to the facilities from one of our contracted wholesalers: Cardinal Health, McKesson, or Twin Med.

Because products are not stored, processed, or shipped from our office location, our MDEG Administrator, Maria Percival, is not always present at our office site.

Sincerely,

Nick Percival, COO

421 Canal Street Suite 201, New Smyrna Beach, Florida 32168
Phone: 832-662-HEAL (4325) Fax: 386-643-1234
WWW.CURITEC.COM

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 5-26-2021

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for DME SUPPLIER OF WOUND CARE SUPPLIES
Nature of MDEG

CURITEC, LLC. 421 CANAL ST., STE 201, NEW SMYRNA BEACH FL 32168
Name and Address of Business for Which MDEG Administrator Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

PERCIVAL (Last Name) MARIA (First Name) GUADALUPE (Middle Name)

MARIA RINCON, MARIA FERNANDEZ
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] NORTHGATE DRIVE (Present Residence Address-Street or RFD) THE WOODLANDS, (City) TX 77380 (State/Zip)

421 CANAL ST. SUITE 201, (Present Business Address) Dates 2018 to Present) NEW SMYRNA BEACH (City) FL 32168 (State/Zip)

CEO/ADMINISTRATOR (Present Position with the MDEG) Dates OCT. 2018 TO PRESENT

Phone: [redacted] Fax: 386-643-1234

Email address: MARIA.PERCIVAL@CURITEC.COM

[redacted] (Date of Birth) LOS ANGELES, (Place of Birth (City, County, State)) COUNTY OF LOS ANGELES, CALIFORNIA

[redacted] (Age) [redacted] (Social Security Number or ITIN) F (Sex)

BROWN (Color of Eyes) BROWN (Color of Hair) 110 LBS. (Weight) 5'1" (Height)

Scars, tattoos or distinguishing marks and/or characteristics NONE BUT IS FLUENT IN SPANISH AND ENGLISH

Are you a citizen of the United States? (Yes) No

If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
OCT 2018 TO PRESENT	CURITEC, LLC. 421 CANAL ST, STE 201 NEW SMYRNA BEACH, FL 32168	5,280
Title	**Description of Duties**	**Name of Supervisor**
CEO & ADMINISTRATOR	OVERSEES ALL OPERATIONS + WORK OF EMPLOYEES	NDPE

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☐ I have not ☒ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ☐ I have not ☒ been the subject of an administrative action whether completed or pending.
3. I have ☐ I have not ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

a) Board Administrative Action: State: _____

b) Date: _____

Case Number: _____

c) Criminal Action: State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG? Yes ☒ No ☐

5 .Will you be employed fulltime with the MDEG? Yes ☒ No ☐

6 .Will you be present at the site of the MDEG during its normal operating hours? Yes ☐ No ☒

If you answer No to questions 4, 5 or 6 please provide a written letter o

SEE LETTER OF EXPLANATION

ATTACH

TAKEN

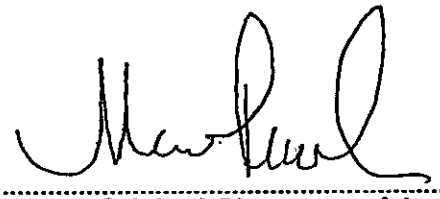
30 D



Date of photograph 5-25-2021

I, MARIA PERCIVAL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.



Original Signature of Applicant

4W

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☒ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: MAXIMUM DME CORPORATION

Physical Address: 200 BRADFORD AVE SUITE J PLACENTIA, CA 92870
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 200 N BRADFORD AVE SUITE J

City: PLACENTIA State: CA Zip Code: 92867

Telephone: 800-762-1511 Fax: 800-762-1511

E-mail: ANGEL@MAXIMUMDME.ORG Website: WWW.MAXIMUMDME.ORG

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8:00AM to 4:00PM Tue: 8:00AM to 4:00PM Wed: 8:00AM to 4:00PM Thu: 8:00AM to 4:00PM Fri: _____ to _____ Sat: _____ to _____ Sun: _____ to _____ Holidays: _____ to _____

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: ANGEL VASQUEZ

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☑ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☑ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.
Name: ANGEL VASQUEZ Telephone: 800-762-1511

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

MEDICARE	7807860001	

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☑

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

ANGEL VASQUEZ
Print Name of Authorized Person

05/26/2021
Date

Board Use Only	Received:_____	Amount: 500 check #0117

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: CALIFORNIA

Parent Company if any: _____

Corporation Name: MAXIMUM DME CORPORATION

Mailing Address: 200 BRADFORD AVE SUITE J

City: PLACENTIA State: CA Zip: 92870

Telephone: 800-762-1511 Fax: 800-762-1511

Contact Person: ANGEL VASQUEZ

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Alan Hugche (Name) 200 N Bradford Ave Suite J Placentia, CA 92870 (Address)

b) David Franklin (Name) 200 N Bradford Ave Suite J Placentia, CA 92870 (Address)

c) Angel Vasquez (Name) 200 N Bradford Ave Suite J Placentia, CA 92870 (Address)

d) _____ (Name) _____ (Address)

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 5/12/2021

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

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

PRODUCER	CONTACT NAME: CHUBB CUSTOMER SERVICE CENTER	
ARTHUR J. GALLAGHER & CO. INS. BROKERS OF CALIF 18201 VON KARMAN AVE 200 IRVINE CA 92612-0000	PHONE (A/C, No, Ext): 866-972-2727	FAX (A/C, No):
	E-MAIL ADDRESS: CHUBBCSC@CHUBB.COM	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : ACE Property And Casualty Insurance Company	20699
INSURED MAXIMUM DME 200 N BRADFORD AVE STE J PLACENTIA CA 92870	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			LSICAD952500873N	01-30-2021	01-30-2022	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ Included
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) [ ] Y/N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A						[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

This certificate is issued as a matter of information only and confers no rights upon the certificate holder. This certificate does not amend, extend or alter the coverage afforded by the policies above. The insurance afforded by the policies described herein is subject to all terms, exclusions and conditions of such policies.

CERTIFICATE HOLDER

NSC – National Supplier Clearinghouse

PO Box 100142
Columbia, SC 29202

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

ALAN HUYCKE, OWNER/ CEO

DAVID FRANKLIN, OWNER

ANGEL VASQUEZ, OWNER / PRESIDENT

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, Ph.D., Secretary of State of the State of California, hereby certify:

Entity Name:	MAXIMUM DME CORPORATION
File Number:	C4281641
Registration Date:	05/24/2019
Entity Type:	DOMESTIC STOCK CORPORATION
Jurisdiction:	CALIFORNIA
Status:	ACTIVE (GOOD STANDING)

As of April 21, 2021 (Certification Date), the entity is authorized to exercise all of its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the Certification Date and does not reflect documents that are pending review or other events that may affect status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 22, 2021.

SHIRLEY N. WEBER, Ph.D.
Secretary of State

Certificate Verification Number: R5496XY

To verify the issuance of this Certificate, use the Certificate Verification Number above with the Secretary of State Certification Verification Search available at bebizfile.sos.ca.gov/certification/index.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG MAXIMUM DME CORPORATION MDEG License # (if applicable) _____

Physical Address 200 N BRADFORD AVE SUITE J

City PLACENTIA State CA Zip 92870

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 8007621511 Website WWW.MAXIMUMDME.COM

Licensing Company Email ANGEL@MAXIMUMDME.ORG

Section 2: Personal Information

First ANGEL Middle _____ Last VASQUEZ

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

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

Mailing Address 200 N BRADFORD AVE SUITE J

City PLACENTIA State CA Zip 92870

Telephone 8007621511 Email ANGEL@MAXIMUMDME.ORG

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
LIFE PACIFIC UNIVERISTY			09/14-06/19	
Address	City		State	Zip
Diploma/Degree obtained, if any				
associates degree				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
A&D MEDICAL SUPPLY			01/19-01/20	
Business Address		City	State	Zip
3848 Campus Dr Ste 117		Newport Beach	92660	
Phone	Title		Number of Employed Hours	
(800) 887-4870	OPERATIONS/ COMPLIANCE		2000+	
Description of Duties				
RAN DAY TO DAY OPERATIONS				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/21/21
Date

I, ANGEL VASQUEZ, **certify that as the MDEG Administrator for**

MAXIMUM DME,

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

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

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

ANGEL VASQUEZ
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/17/2021
Date

Board Use Only	Date Received:

4X

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☒ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: Monitor Medical, Inc.

Physical Address: 12999 Jess Pirtle Blvd. Sugar Land, TX 77478
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 12999 Jess Pirtle Blvd.

City: Sugar Land State: TX Zip Code: 77478

Telephone: (281)240-7222 Fax: (281)240-1164

E-mail: kelly.boettcher@monitormedical.com Website: www.monitormedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9am to 5pm, Tue: 9am to 5pm, Wed: 9am to 5pm, Thu: 9am to 5pm Fri: 9am to 5pm, Sat: Closed to Sun: Closed to Holidays: to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Richard Webb

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☒ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: Richard Webb Telephone: 866-634-0177

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

043-445-0001- TX Medicare _____ _____

195881101- TX Medicaid _____ _____

_____ _____ _____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: Richard E. Webb

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Richard Webb
Print Name of Authorized Person

5-4-2021
Date

Board Use Only	Received:	Amount: $500 Check # 4559

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Texas

Parent Company if any: _____

Corporation Name: Monitor Medical, Inc.

Mailing Address: 12999 Jess Pirtle Blvd.

City: Sugar Land State: TX Zip: 77478

Telephone: 281-240-7222 Fax: 281-240-1164

Contact Person: Kelly Boettcher

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Richard Webb [redacted] Winding River Rd. Richmond, TX 77406
Name Address

b) N/A
Name Address

c) N/A
Name Address

d) N/A
Name Address

2) Provide the number of shares issued by the corporation. 1,000

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 04/18/1991

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

MONITOR MEDICAL

Corporate Management & Owners

Richard Webb, CEO – Owner 100%

Priti Vasa, Director of Finance

Irfan Mirza, Director of Information Systems

Office Management

Location Manager: Kelly Boettcher

Management Hours: 10am-5pm

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

MONITOR MEDICAL INC
PO BOX 2527
SUGAR LAND TX 77487

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

MONITOR MEDICAL INC
12999 JESS PIRTLE BLVD STE 200
SUGAR LAND, TX 77478

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

WHOLESALE DISTRIBUTOR OF COMPRESSED MEDICAL GAS

DEVICE DISTRIBUTOR

License # 1001608
Expires: December 16, 2022

NON-TRANSFERABLE

Commissioner

511676

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
Consumer Protection Division
PO Box 149347, Austin, TX 78714
(512) 834-6660

Name	MONITOR MEDICAL INC MONITOR MEDICAL INC	License Type	Multiple Products
Address	12999 JESS PIRTLE BLVD STE 200 SUGAR LAND TX 77478	License Number	1001608
Inspection Type	Periodic/Routine	Inspection Number	249698
Inspector	WILSON, TEDRICK D	Inspection Date	03/09/2021

NOTICE OF INSPECTIONAL OBSERVATIONS

This notice is to acknowledge that the Texas Department of State Health Services (DSHS) conducted an inspection of your business on the date listed above. The information that has been gathered is subject to further department review and you may receive additional correspondence as a result.

There is no deficiency/violation cited or noted within the scope of this inspection/visit.

Inspector:

WILSON, TEDRICK D

Date: 03/09/2021

Firm Representative:

Jason Joseph

Date: 03/09/2021

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/12/2021

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

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

PRODUCER	Dyer Insurance Agency Inc P. O. Box 1537 1018 Ridge Rd Rockwall TX 75087	CONTACT NAME:	Don Dyer
		PHONE (A/C, No, Ext):	(972) 771-8301
		FAX (A/C, No):	(972) 771-8889
		E-MAIL ADDRESS:	Don@Dyerinsurance.com
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A:	State National Insurance Company
		INSURER B:	Liberty Mutual Insurance Company
		INSURER C:	
		INSURER D:	
		INSURER E:	
		INSURER F:	
INSURED	Monitor Medical, Inc. 12999 Jess Pirtle Blvd Sugar Land TX 77478		

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			VGM D1020g3647-14	01/11/2021	01/11/2022	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Medical Professional						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER							$
B	AUTOMOBILE LIABILITY			BAW57236701	07/18/2020	07/18/2021	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	ANY AUTO						BODILY INJURY (Per person)	$
	X OWNED AUTOS ONLY; SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY; X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)		N/A				E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

PTAN 043-44500001

AI 007331

CERTIFICATE HOLDER

National Suppliers Clearing House
P O Box 100142
Columbia SC 29202-

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Don Dyer

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

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

Jose A. Esparza
Deputy Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Deputy Secretary of State of Texas, does hereby certify that the document, Articles Of Incorporation for MONITOR MEDICAL, INC. (file number 118983900), a Domestic For-Profit Corporation, was filed in this office on April 18, 1991.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on June 10, 2021.

Jose A. Esparza
Deputy Secretary of State

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Monitor Medical, Inc. MDEG License # (if applicable) _____

Physical Address 12999 Jess Pirtle Blvd.

City Sugar Land State TX Zip 77478

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (281)240-7222 Website www.monitormedical.com

Licensing Company Email kelly.boettcher@monitormedical.com

Section 2: Personal Information

First Richard Middle Edward Last Webb

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

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

Mailing Address [redacted] Winding River Rd.

City Richmond State TX Zip 77406

Telephone [redacted] Email richard.webb@monitormedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
The University of Texas Health Science Center at Houston		1982-1992	
Address	**City**	**State**	**Zip**
P.O. Box 20036	Houston	TX	77225
Diploma/Degree obtained, if any			
Bachelor of Science in Respiratory Therapy			
School Name		**From - To (MM/YY – MM/YY)**	
Sinclair Community College		01/1975-06/1979	
Address	**City**	**State**	**Zip**
444 West Third Street	Dayton	OH	45402-1421
Diploma/Degree obtained, if any			
Associate in Applied Science Respiratory Therapy			
School Name		**From - To (MM/YY – MM/YY)**	
Alter HS		1970-1974	
Address	**City**	**State**	**Zip**
940 E. David Rd.	Kettering	OH	45429
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted] Winding River Rd	Richmond	TX	77406
From - To (MM/YY – MM/YY)	Address	City	State	Zip
	3708 Elkins	Sugar Land	TX	~~77487~~ 77479
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name		From - To (MM/YY – MM/YY)	
Monitor Medical, Inc.		04/1991-current	
Business Address	**City**	**State**	**Zip**
12999 Jess Pirtle Blvd	Sugar Land	TX	77478
Phone	**Title**	**Number of Employed Hours**	
281-240-7222	CEO	40+ hours per week	
Description of Duties			
Provide respiratory therapy training to employees. Provide Respiratory Therapy education to patients.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

06/10/21
Date

I, Richard Webb **, certify that as the MDEG Administrator for**

Monitor Medical, Inc. ,

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

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

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

Richard Webb
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/10/2021
Date

Board Use Only	Date Received:

4Y

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5
☒ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare LLC dba Preferred Medical

Physical Address: 405 Sterling St Doors E1-E4 Camp Hill PA 17011
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3230 Fax: none

E-mail: hbasley@ndc-inc.com Website: www.preferredmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 730 to 430 Tue: 730 to 430 Wed: 730 to 430 Thu: 730 to 430 Fri: 730 to 430 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Tam Marple

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

none

We only ship to patients no other contact

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley

Print Name of Authorized Person

1/20/2024

Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: MDC Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Beasley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
MDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: See above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
	INSURER(S) AFFORDING COVERAGE / NAIC #
	INSURER A: Medmarc Casualty Insurance Company 22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

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

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General Strong | Interpreter | Defendant Mark Tyler Seitz

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant **Mark Tyler Seitz** pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years 11 Months 29 Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months 0 Days 3 Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years 11 Months 29 Days

$350.00 Fine

Special Conditions :

I hereby certify that this is a true and exact copy of the original

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton | III Div | 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

4Z

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5
☒ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare LLC dba Preferred Medical

Physical Address: 173 Nabco Ave Conway AR 72032
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3225 Fax: None

E-mail: tbeasley@ndc-inc.com Website: www.preferredmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7:30 to 4:30 Tue: 7:30 to 4:30 Wed: 7:30 to 4:30 Thu: 7:30 to 4:30 Fri: 7:30 to 4:30 Sat: None to Sun: None to Holidays: None to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: David Hicks

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

None _____ _____ _____

We only drop ship to patients no other contact

_____ _____ _____

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner — Name: _____
- Advanced Practitioner of Nursing — Name: _____
- Physician's Assistant — Name: _____
- Physical Therapist — Name: _____
- Occupational Therapist — Name: _____
- Registered Nurse — Name: _____
- Respiratory Therapist — Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley
Print Name of Authorized Person

11/20/2021
Date

Board Use Only	Received:_____	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: MX Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Bagsley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
MX Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: See above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/24/2020

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

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

PRODUCER	CONTACT NAME: Willis Towers Watson Certificate Center	
Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	PHONE (A/C, No, Ext): 1-877-945-7378	FAX (A/C, No): 1-888-467-2378
	E-MAIL ADDRESS: certificates@willis.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Medmarc Casualty Insurance Company	22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? ☐ N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

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

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General _____ Interpreter _____ Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant Mark Tyler Seitz pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years 11 Months 29 Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months 0 Days 3 Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years 11 Months 29 Days

$350.00 Fine

I hereby certify that this is a true and exact copy of the original

Special Conditions :

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

By: D.C.

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton III Div 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

4AA

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership - Pages 1,2,3,6
☐ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare LLC dba Preferred Medical

Physical Address: 13949 Alvarez Rd Jacksonville FL 32218
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3225 Fax: none

E-mail: hbeasley@ndc-inc.com Website: www.preferedmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7:30 to 4:30 Tue: 7:30 to 4:30 Wed: 7:30 to 4:30 Thu: 7:30 to 4:30 Fri: 7:30 to 4:30 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Manny Antomattey

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

None

We only dropship patients no other contact

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley
Print Name of Authorized Person

1/20/2021
Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: NDC Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Beasley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
NDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: See above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A: Medmarc Casualty Insurance Company 22241 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE



© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General _____ Interpreter _____ Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant **Mark Tyler Seitz** pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years 11 Months 29 Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months 0 Days 3 Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years 11 Months 29 Days

$350.00 Fine

Special Conditions :

I hereby certify that this is a true and exact copy of the original

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

By: D. Owens D.C.

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton Div 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

4BB

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership - Pages 1,2,3,6
☐ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare LLC dba Preferred Medical

Physical Address: 830 S St Paul Ave Kansas City KS 66105
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3230 Fax: none

E-mail: hbasley@ndc-inc.com Website: www.preferredmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7:30 to 4:30 Tue: 7:30 to 4:30 Wed: 7:30 to 4:30 Thu: 7:30 to 4:30 Fri: 7:30 to 4:30 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Russ Sanders

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.
Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

None

We only drop ship product to patient no other Contact

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Baster
Print Name of Authorized Person

11/20/2021
Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: MDC Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Beasley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
MDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: See above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: Medmarc Casualty Insurance Company — 22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE



© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359



AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

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

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General _____ Interpreter _____ Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant **Mark Tyler Seitz** pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years **11** Months **29** Days Hours @ % [ ] Suspended PROB TERM

Suspend All But **5 DAYS** @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months **0** Days **3** Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years **11** Months **29** Days

$350.00 Fine

I hereby certify that this is a true and exact copy of the original

Special Conditions :

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

BY

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton III Div 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

4CC

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☒ Partnership - Pages 1,2,3,6
☐ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare, LLC dba Preferred Medical

Physical Address: 1000 Schroeder Bldg 1 Ste 101 Waco TX 76710
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 615 366 3230 Fax: none

E-mail: hbeasley@ndc-inc.com Website: www.preferredmedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7:30 to 4:30 Tue: 7:30 to 4:30 Wed: 7:30 to 4:30 Thu: 7:30 to 4:30 Fri: 7:30 to 4:30 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Jay Piscacek

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

None

We Only dropship to patients no other Contact

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley
Print Name of Authorized Person

1/20/2021
Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: NDC Intermediate Holdings LLC

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3230 Fax: none

Contact Person: Tammy Bagsley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
NDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: see above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: Medmarc Casualty Insurance Company — 22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER		
See Page 1		
CARRIER	NAIC CODE	EFFECTIVE DATE: See Page 1
See Page 1	See Page 1	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

Printed on 10/2/2007 at 12:15:09

General Sessions Disposition

Warrant #: GS335150

CRIMINAL COURT OF DAVIDSON COUNTY

[ ] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

Assistant Attorney General _____ Interpreter _____ Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant **Mark Tyler Seitz** pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty	[ ] Found Guilty	[ ] Not Guilty	[ ] 40-35-313	[ ] 40-15-105
[ ] Dismissed	[ ] Dismissed on Costs	[ ] Dismissed ROS	[ ] Dismissed, Cost to Pros	
[ ] Nolled	[ ] Nolo Contendere		[ ] Retired on Costs	[ ] Retired

SENTENCE

Years **11** Months **29** Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months **0** Days **3** Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years **11** Months **29** Days

$350.00 Fine

Special Conditions :

I hereby certify that this is a true and exact copy of the original

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

BY: D.C.

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton Div III 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

4DD

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☑ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: Sleep Central

Physical Address: 104 Max Hurt Drive, Murray, KY 42071
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 3600 Vineland Rd, Ste 114

City: Orlando State: FL Zip Code: 32811

Telephone: 270-759-8889 Fax: 270-753-6339

E-mail: provider.services@rotech.com Website: NA

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9-12 to 1-4 Tue: 9-12 to 1-4 Wed: 9-12 to 1-4 Thu: 9-12 to 1-4 Fri: 9-12 to 1-4 Sat: to Sun: to Holidays: to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Kevin Watkins

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☑ Respiratory Equipment** (CPAP, RAD, etc.)
☐ Life-sustaining equipment**
☑ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: Please see attached

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: Kevin Watkins Telephone: 270-759-8889

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

0235970008 Medicare		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☑ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE MDEG LICENSE 161510 NV BOP

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Robin L Menchen

Original Signature of Person Authorized to Submit Application, no copies or stamps

Robin Menchen
Print Name of Authorized Person

04/30/2021
Date

Board Use Only	Received:_____	Amount: 500 check #4591177

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: Rotech Healthcare Inc.

Corporation Name: Holland Medical Services, Inc.

Mailing Address: 3600 Vineland Rd Ste 114

City: Orlando State: FL Zip: 32811

Telephone: 407-822-4600 Fax: 407-297-4029

Contact Person: Suzy Martinez

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Please see attached
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1,000

3) What was the price paid per share? The equity of the company was revalued at $490,494.27 ~~upon emerging from bankruptcy~~

4) What date did the corporation actually receive the cash assets? No cash was exchanged

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors. Please see attached

ROTECH HEALTHCARE INC.

MEMO

To:

From: Sleep Central

Date:

Re: Products and Services

Below are the products and services Sleep Central will provide:

* Blood Glucose Monitors and/or Supplies (mail order)
* Blood Glucose Monitors and/or Supplies (non-mail order)
* Continuous Positive Airway Pressure (CPAP) Devices and/or Supplies
* Negative Pressure Wound Therapy Pumps and/or Supplies (NPWT)
* Neuromuscular Electrical Stimulators (NMES) and/or Supplies
* Respiratory Assist Devices (RAD)
* Tracheostomy Supplies
* Transcutaneous Electrical Nerve Stimulators (TENS) and/or Supplies
* Ventilators: All Types - Not CPAP or RAD

Thank you.

Zimbra penny.lohman@rotech.com

National Provider Identifier rhi 161510

From : customerservice@npienumerator.com Thu, Jun 12, 2014 03:16 PM

Subject : National Provider Identifier

To : penny lohman <penny.lohman@rotech.com>

Enumeration Date: March 29, 2006

A request for a National Provider Identifier for the following provider was recently submitted to https://nppes.cms.hhs.gov, and you were listed as the contact person. This is to inform you that the request was successfully processed and the following NPI has been assigned:1235190232.

HOLLAND MEDICAL SERVICES INC
EIN: =====0731
Other Organization Name: SLEEP CENTRAL
Parent LBN: ROTECH HEALTHCARE INC
Parent TIN: =====8870

Practice Location:
104 Max Hurt Dr
Murray, KY 42071-7847

Other Identification Numbers:
Issuer: MEDICARE NSC
Number: 0235970008
State: KY

Provider Taxonomies:
Taxonomy: 332BC3200X
Details: Durable Medical Equipment & Medical Supplies/Customized Equipment

Taxonomy: 332BP3500X
Details: Durable Medical Equipment & Medical Supplies/Parenteral & Enteral Nutrition

Taxonomy: 332BX2000X
Details: Durable Medical Equipment & Medical Supplies/Oxygen Equipment & Supplies

Taxonomy: 335E00000X
Details: Prosthetic/Orthotic Supplier

Taxonomy: 332B00000X
Details: Durable Medical Equipment & Medical Supplies
This is the Primary Taxonomy.

If you have any questions about this notification you may contact the NPI Enumerator at:
NPI Enumerator
PO Box 6059
Fargo, ND 58108-6059
1-800-465-3203 (NPI Toll-Free)
1-800-692-2326 (NPI TTY)
customerservice@npienumerator.com

You may view or change this provider's NPPES information by logging onto the NPPES website at https://nppes.cms.hhs.gov.

Please note: If you are not the provider, you are required to inform the provider of the information in this e-mail and furnish a copy of this notification to the provider.

Shareholder Information

Capital Research and Management, LP **333 South Hope Street** **55th Floor** **Los Angeles, CA 90071**	**46.5%**
Silver Point Finance **Two Greenwich Plaza** **1st Floor** **Greenwich, CT 06830**	**28.6%**
Vendor Capital Management **7 Times Square #3505** **New York, NY 10056**	**20.8%**
Fidelity Management & Research Company **82 Devonshire Street #FSA** **Boston, MA 02109**	**4.1%**

Holland Medical Services, Inc. is a 100% wholly owned subsidiary of Rotech Healthcare Inc. located at
3600 Vineland Rd Ste 114, Orlando, FL 32811

OFFICERS FOR ALL SUBSIDIARIES
OWNED BY
ROTECH HEALTHCARE INC

Timothy C. Pigg, CEO & President

Home Address:
[redacted] Lynwood Road
Sherrills Ford, NC 28673
Home No. [redacted]
Office No.(407) 822-4600
Social Security No. [redacted]
Date of Birth [redacted]

Thomas J. Koenig, CFO

Home Address:
[redacted] Stone Ridge Drive
Springboro, OH 45066
Home No.: [redacted]
Office No.: (407) 822-4600
Social Security No.: [redacted]
Date of Birth: [redacted]

Robin L. Menchen, Chief Operating Officer

Home Address:
[redacted] Canyon View Ct
Magnolia, TX 77355-3057
Home No. [redacted]
Office No. (407) 822-4600
Social Security No. [redacted]
Date of Birth [redacted]

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Holland Medical Services, Inc.

Nevada Business Identification # NV20212060143
Expiration Date: 04/30/2022

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/02/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202104021563885
You may verify this certificate online at http://www.nvsos.gov

State of Florida
Department of State

I certify from the records of this office that HOLLAND MEDICAL SERVICES, INC. is a corporation organized under the laws of the State of Florida, filed on May 3, 1993, effective April 29, 1993.

The document number of this corporation is P93000032441.

I further certify that said corporation has paid all fees due this office through December 31, 2020, that its most recent annual report/uniform business report was filed on May 7, 2020, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of April, 2021



Secretary of State

Tracking Number: 2391118987CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

In the name and by the Authority of the

Commonwealth of Kentucky

Kentucky Board of Durable Medical Equipment Suppliers

Sleep Central

104 Max Hurt Drive Murray KY 42071

has fulfilled the provisions of the Kentucky Revised Statutes and is hereby licensed as a

Home Medical Equipment and Services Provider

and is hereby authorized to practice as a Home Medical Equipment and Services Provider within the Commonwealth of Kentucky.

Given under our hands and the Seal of the Department of Professional Licensing

/s Jeff W. Knight

Chair

License Number: 169913
Issue Date: May 1, 2012
Expire Date: September 30, 2022

ROTEHEA-01 KPETERS

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 6/1/2020

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

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

PRODUCER	CONTACT NAME: Karen A. Peters, CPCU	
Rose & Kiernan, Inc. 99 Troy Road East Greenbush, NY 12061	PHONE (A/C, No, Ext): 4298	FAX (A/C, No):
	E-MAIL ADDRESS: kpeters@rkinsurance.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : State National Insurance Co.	12831
INSURED	INSURER B : ACE American Insurance Co.	22667
Rotech Healthcare Inc. 3600 Vineland Road, Suite 114 Orlando, FL 32811-6460	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY								
	CLAIMS-MADE X OCCUR			VGM D1019 G6289-1	6/1/2020	6/1/2021	EACH OCCURRENCE	$	1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	5,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	3,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO			ISAH25298627	6/1/2020	6/1/2021	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	10,000,000
	X EXCESS LIAB CLAIMS-MADE			VGMUM101962901	6/1/2020	6/1/2021	AGGREGATE	$	10,000,000
	DED RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N	N/A		WLRC6692421A	6/1/2020	6/1/2021	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
A	Healthcare Prof Liab			VGM D1019 G6289-1	6/1/2020	6/1/2021	Each Claim		1,000,000
A				VGM D1019 G6289-1	6/1/2020	6/1/2021	Aggregate		3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Job Lawson # 161510
Evidence of Insurance for Rotech Healthcare Inc. and Subsidiaries.

CERTIFICATE HOLDER

Holland Medical Services, Inc
SLEEP CENTRAL
104 MAX HURT DRIVE
MURRAY, KY 42071

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

State of Florida
Department of State

I certify from the records of this office that HOLLAND MEDICAL SERVICES, INC. is a corporation organized under the laws of the State of Florida, filed on May 3, 1993, effective April 29, 1993.

The document number of this corporation is P93000032441.

I further certify that said corporation has paid all fees due this office through December 31, 2020, that its most recent annual report/uniform business report was filed on May 7, 2020, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fourteenth day of April, 2021



Secretary of State

Tracking Number: 2391118987CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Sunbiz

(Step 3 of 3) Thank you for your payment.

Please print this receipt and keep it for your records.

Tracking Number : 2391118987CU

Document Number : P93000032441

Payment Amount: $8.75

Receipt Number: 3804329623

Transaction Date: 04/14/2021 11:32 AM

Payment Type: VISA

Account Number: *4058

Darlene Nases

From: Susan Martinez <susan.martinez@rotech.com>
Sent: Friday, June 18, 2021 9:12 AM
To: Darlene Nases
Cc: provider services
Subject: Re: MDEG Application - Sleep Central - Need more information
Attachments: _NV BOP Administrator Application.pdf

Good Morning,

Please see the attached requested MDEG Administrator form for our facility, Sleep Central located at 104 Max Hurt Drive, Murray, KY 42071. The current administrator is as follows:

Kevin Lee Watkins
kevin.watkins@rotech.com
(270) 759-8889

Please let us know if you need anything else to complete the application process.

Thank you,

Suzy Martinez
Provider Services Manager
3600 Vineland Road, Suite 114
Orlando, FL 32811
Phone 407-822-4600 ext. 104755
e-Fax 866-617-5984
Fax 407-297-4029



This communication, including any attachments, may contain confidential, proprietary and/or privileged information that is intended to be read only by the individual or entity to which it is addressed. If you are not the intended recipient, you are on notice that any review, disclosure, copying, distribution, or use of the contents of this message is strictly prohibited. If you have received this message in error, please notify the sender immediately and delete or destroy any copy of this message.

From: "Darlene Nases" <dnases@pharmacy.nv.gov>
To: "provider services" <provider.services@rotech.com>
Sent: Friday, May 21, 2021 1:08:38 PM
Subject: MDEG Application - Sleep Central - Need more information

To whom it may concern:

I received your MDEG Application and was reviewing the documentation.
Going forward, we are requesting an MDEG Administrator form to be completed along with the application.

Could you please provide this information and send in to our office?

Regards,

Darlene Nases
Licensing Specialist

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 06/17/2021

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand comer.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Sleep Central
Nature of MDEG

104 Max Hurt Drive, Murray, KY 42071
Name and Address of Business for Which MDEG Administrator Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Watkins (Last Name) Kevin (First Name) Lee (Middle Name)

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Enterprise Ln (Present Residence Address-Street or RFD) Gilbertsville (City) KY 42044 (State/Zip)

104 Max Hurt Dr (Present Business Address) 04/17/17 - present (Dates) Murray (City) KY 42071 (State/Zip)

General Manager (Present Position with the MDEG) 04/17/17 - present (Dates)

Phone: [redacted] Fax: 270-753-6339

Email address: ~~KWATKINS~~ Kevin.Watkins@Rotech.com

[redacted] (Date of Birth) Paducah McCracken KY (Place of Birth (City, County, State))

36 (Age) [redacted] (Social Security Number or ITIN) M (Sex)

Blue (Color of Eyes) Brown (Color of Hair) 230 (Weight) 5'9" (Height)

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? (Yes) No

If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
04 2017	Rotech Healthcare Inc 104 MAX Hurt Murray KY 42071	11,000
Title	**Description of Duties**	**Name of Supervisor**
General Manager	Day to Day operations	Christina Adams

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

I have ➧ I have not ➧ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ➧ I have not ➧ been charged, arrested or convicted of a felony or misdemeanor.
2. I have ➧ I have not ➧ been the subject of an administrative action whether completed or pending.
3. I have ➧ I have not ➧ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

a) Board Administrative Action: State:_____

b) Date: _____

Case Number: _____

c) Criminal Action: State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG? Yes ➧ No ➧

5 .Will you be employed fulltime with the MDEG? Yes ➧ No ➧

6 .Will you be present at the site of the MDEG during its normal operating hours? Yes ➧ No ➧

If you answer No to questions 4, 5 or 6 p of explanation.

.....

.....

.....

.....

.....



H PHOTOGRAPH

N WITHIN LAST

)AYS HERE

aph 06-16-2021

I, Kevin Lee Watkins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

Original Signature of Applicant

4EE

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐New MDEG ☑ Ownership Change
(Please provide current license number if making changes: MP or MW MP00524)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6
☑ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: United States Medical Supply, LLC

Physical Address: 8260 NW 27TH ST STE #401, Doral, FL 33122
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 8260 NW 27TH ST STE #403, Attn: Licensing Dept

City: Doral State: FL Zip Code: 33122

Telephone: 800-787-6331 Fax: 305-455-3587

E-mail: Licensing@usmed.com Website: www.usmed.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9AM to 5PM Tue: 9AM to 5PM Wed: 9AM to 5PM Thu: 9AM to 5PM Fri: 9AM to 5PM Sat: Closed to Sun: Closed to Holidays: Closed to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Timothy Cady

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☑ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: Insulin Infusion Pumps and Supplies

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.
Name: _____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

1129690001 - PTAN		
See Attachment - Medicaid		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☑ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☑ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner — Name: N/A
- Advanced Practitioner of Nursing — Name: N/A
- Physician's Assistant — Name: N/A
- Physical Therapist — Name: N/A
- Occupational Therapist — Name: N/A
- Registered Nurse — Name: N/A
- Respiratory Therapist — Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Timothy Cady

Print Name of Authorized Person

6/14/2021

Date

Board Use Only	Received:	Amount: 500 check # 12050

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: US MED Acquisition, Inc.

Corporation Name: United States Medical Supply, LLC

Mailing Address: 8260 NW 27TH ST STE #403, Attn: Licensing Dept.

City: Doral State: FL Zip: 33122

Telephone: 877-345-5813 Fax: 305-455-3587

Contact Person: Jessenia Rodriguez

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) US MED Acquisition, Inc. (Name) 8260 NW 27TH ST STE #401, Doral, FL 33122 (Address)

b) _____ (Name) _____ (Address)

c) _____ (Name) _____ (Address)

d) _____ (Name) _____ (Address)

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? Date of Sale: 7/21/2021

5) Provide a copy of the corporation's stock register evidencing the above information N/A

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Medicaid Provider Numbers - United States Medical Supply, LLC

State	Provider Number
Alabama	9710090
Alaska	1021915
Arizona	773607
Arkansas	132224741
California	2669140
Colorado	87804573
Connecticut	3100443
Delaware	1700889227
Florida	15194700
Georgia	000762649A
Hawaii	65-0670195 (535362)
Idaho	1700889227
Illinois	650670195001
Indiana	200149910A
Iowa	715532
Kansas	100298320A
Kentucky	90612292
Louisiana	1699829
Maine	186950000
Maryland	19502200
Michigan	4960848
Minnesota	674817100
Mississippi	440477
Missouri	628723603
Montana	1700889227
Nebraska	65067019500
Nevada	1700889227
New Hampshire	3107751
New Jersey	516881
New Mexico	45974314
New York	2756861
North Carolina	65-0670195
North Dakota	1461730
Ohio	2050006
Oklahoma	200064720A
Oregon	28158
Pennsylvania	72690800002
Rhode Island	9690001
South Carolina	DM0953
South Dakota	9167870
Tennessee	4582037
Texas	151534801
Utah	1700889227
Vermont	1011832
Virginia	1700889227
Washington	1016883
West Virginia	227344000
Wisconsin	100050169
Wyoming	121587600

State of Florida
Department of State

I certify from the records of this office that UNITED STATES MEDICAL SUPPLY, LLC is a limited liability company organized under the laws of the State of Florida, filed on August 10, 2015, effective May 15, 1996.

The document number of this limited liability company is L15000134708.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on April 25, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifteenth day of June, 2021



Secretary of State

Tracking Number: 6987670210CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/3/2021

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

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

PRODUCER
Arthur J. Gallagher Risk Management Services, Inc.
9155 S Dadeland Blvd Suite 1112
Miami FL 33156

CONTACT NAME:
PHONE (A/C, No, Ext): 305-592-6080 | FAX (A/C, No): 305-592-4049
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Arch Specialty Insurance Company	21199
INSURER B : American Zurich Insurance Company	40142
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED UNITSTA-31
United States Medical Supply, LLC
8260 NW 27th St Ste 401
DORAL , FL 33122

COVERAGES **CERTIFICATE NUMBER:** 1436128014 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			BAP 0184650-06	2/23/2021	2/23/2022	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 2,000,000
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$ 2,000,000
	DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC 0233413-05	2/23/2021	2/23/2022	X PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory In NH)		N/A				E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Misc Med Prof Prof Liab._Claims Made			FLP005820705	2/23/2021	2/23/2022	Occurence Aggregate	$1,000,000 $3,000,000

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

CERTIFICATE HOLDER

United States Medical Supply LLC
8260 NW 27th Street, #401
Miami FL 33122
USA

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

United States Medical Supply, LLC

List of Owners/Officers/Directors

Name	Title	Address
Timothy Cady	President	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Mark Howard	CEO	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Jeff Abramoff	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Kurt Hilzinger	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
John Weber	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
US Med Acquisition, Inc.	100% Owner	8260 NW 27TH ST STE 401 Doral, FL 33122

8260 NW 27th St. Suite 401, Doral, FL 33122
Phone: 877-345-5813 | Fax: 305-455-3587
Email: Licensing@usmed.com

June 15, 2021

Via FedEx



Nevada Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: United States Medical Supply, LLC - License # MP00524

Dear Sir or Madam:

This letter provides notice of a change in the indirect ownership of United States Medical Supply, LLC which holds the above referenced permit. Effective July 21, 2021, US MED Buyer, inc. will become the sole shareholder of US MED Acquisition, Inc. the facility's parent company. The enclosed organizational chart shows the ownership structure after the transaction. As stated above, this change took place two levels above the operating entity.

Importantly United States Medical Supply, continues to be the direct owner of the facility. There has been a change in officer's, but the facility will:

- Retain the same EIN
- Retain the same name
- Retain the same location
- Retain the same employees

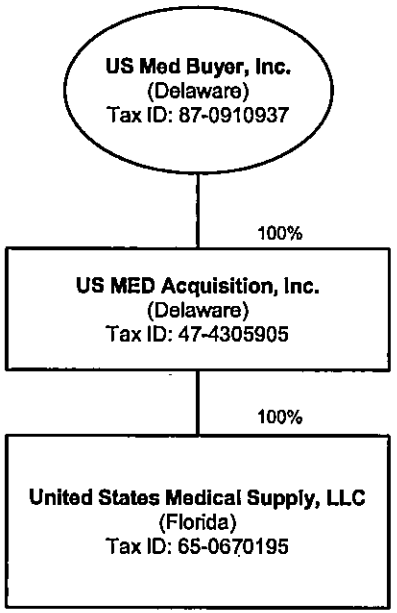
Please let us know if you require any additional information at licensing@usmed.com.

Sincerely,

Mary Ellen Conway

Mary Ellen Conway
Chief Compliance Officer

United States Medical Supply, LLC – Post-Closing Structure Chart



NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: United States Medical Supply, LLC MDEG License # (if applicable): _____

Physical Address: 8260 NW 27TH ST STE #401

City: Doral State: FL Zip: 33122

Mailing Address (if different from physical address): 8260 NW 27TH ST STE #403

City: Doral State: FL Zip: 33122

Telephone: 800-787-6331 Website: www.usmed.com

Licensing Company Email: Licensing@usmed.com

Section 2: Personal Information

First: Mary Ellen Middle: _____ Last: Conway

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

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

Mailing Address: [redacted] NW 27TH ST STE [redacted]

City: Doral State: FL Zip: 33122

Telephone: [redacted] Email: Licensing@usmed.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Georgetown University - School of Nursing		08/77-05/81	
Address	City	State	Zip
3700 O St NW	Washington	DC	20057
Diploma/Degree obtained, if any			
Bachelor of Science - Nursing			

School Name		From - To (MM/YY – MM/YY)	
Immaculata College Prep		09/73-05/77	
Address	City	State	Zip
	Washington	DC	20015
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/07-present	[redacted] Haviland Drive	Bethesda	MD	20817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
US MED, LLC			09/16-present	
Business Address		**City**	**State**	**Zip**
8260 NW 27TH ST STE #403		Doral	FL	33122
Phone	**Title**		**Number of Employed Hours**	
877-345-5813	Chief Compliance Officer		40 hours a week	
Description of Duties				
Chief Compliance Officer for DME and Pharmacy operations				

Business Name			From - To (MM/YY – MM/YY)	
Capital Healthcare Group, LLC			09/99-Present	
Business Address		**City**	**State**	**Zip**
6305 Haviland Drive		Bethesda	MD	20817
Phone	**Title**		**Number of Employed Hours**	
301-896-0193	Consultant, President		20 hours a week	
Description of Duties				
Consultant				

Business Name			From - To (MM/YY – MM/YY)	
Thompson Powers, LLC			09/98-09/99	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Director of Post Acute Services		40 hours a week	
Description of Duties				
Consultant				

Business Name			From - To (MM/YY – MM/YY)	
Personal Touch Home Care			07/93-09/98	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Administrator/Regional Director		40 hours a week	
Description of Duties				
Field nurse and administrator				

Business Name			From - To (MM/YY – MM/YY)	
Staff Builders Home Health Care			12/90-07/93	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Regional Director of Pediatrics		40 hours a week	
Description of Duties				
Field nurse and administrator				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Boston Children's Hospital			09/81-08/83	
Business Address		City	State	Zip
		Boston	MA	
Phone	Title		Number of Employed Hours	
	Staff Nurse		40 hours a week	
Description of Duties				
Full time staff nurse on pediatric medical floor				

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-23-21
Date

I, Mary Ellen Conway, **certify that as the MDEG Administrator for**

United States Medical Supply, LLC,

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

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

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

Mary Ellen Conway
Print Name (First, Last)

Mary Ellen Conway
Original Signature (electronic, copies or stamps not accepted)

6-23-21
Date

Board Use Only	Date Received: _____

4FF

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(Check only) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐New MDEG ☒ Ownership Change
(Please provide current license number if making changes: MP or MW MP00897)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☒ Non Publicly Traded Corporation – Pages 1,2,3,5
☐ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: US MED, LLC

Physical Address: 1480 NW 79th Avenue, Miami, FL 33126
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 8260 NW 27th ST STE #403, Attn: Licensing Dept.

City: Doral State: FL Zip Code: 33122

Telephone: (800) 787-6331 Fax: (305) 455-3587

E-mail: Licensing@usmed.com Website: www.usmed.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9 am to 5 pm Tue: 9 am to 5 pm Wed: 9 am to 5 pm Thu: 9 am to 5 pm Fri: 9 am to 5 pm Sat: Closed to Sun: Closed to Holidays: Closed to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Timothy Cady

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☒ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: CPAP Devices & supplies, Urological Supplies

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: Todd Giller, CRT # RC2820 Telephone: 877-876-3363

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

4146440001 - PTAN		
See Attachment - Medicaid		

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: N/A
- Advanced Practitioner of Nursing Name: N/A
- Physician's Assistant Name: N/A
- Physical Therapist Name: N/A
- Occupational Therapist Name: N/A
- Registered Nurse Name: N/A
- Respiratory Therapist Name: N/A

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Timothy Cady

Print Name of Authorized Person

6/14/2021

Date

Board Use Only	Received:_____	Amount: 500 check # 125046

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: US MED Acquisition, Inc.

Corporation Name: US MED, LLC

Mailing Address: 8260 NW 27TH ST STE #403, Attn: Licensing Dept.

City: Doral State: FL Zip: 33122

Telephone: 877-345-5813 Fax: 305-455-3587

Contact Person: Jessenia Rodriguez

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) US MED Acquisition, Inc. 8260 NW 27TH ST STE #401, Doral, FL 33122
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? Date of Sale: 7/21/2021

5) Provide a copy of the corporation's stock register evidencing the above information N/A

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Medicaid Provider Numbers - US MED, LLC

State	Provider Number
Alabama	137917
Alaska	1624492
Arizona	580258
Arkansas	166398741
California	960140
Colorado	84857544
Connecticut	8048206
Delaware	1811097504
Florida	16979800
Georgia	003133088A
Hawaii	61-1339483 (594748)
Idaho	1811097504
Illinois	611339483001
Indiana	200972060A
Iowa	208753
Kansas	200737930A
Kentucky	7100038430
Louisiana	2349066
Maine	433081100
Maryland	330208300
Massachussets	110150820A
Michigan	4998747
Minnesota	637903000
Mississippi	8304576
Missouri	629630609
Montana	1811097504
Nebraska	10025519700
Nevada	1811097504
New Hampshire	3112960
New Jersey	580210
New Mexico	89339771
New York	3862815
North Dakota	1458965
Ohio	2766396
Oklahoma	200285920A
Oregon	218108
Pennsylvania	1026305880001
Rhode Island	4146440
South Carolina	DM1260
South Dakota	9164650
Tennessee	4582505
Texas	198070801
Utah	1811097504
Vermont	1015385
Virginia	1811097504
Washington	1025319
West Virginia	3910005911
Wisconsin	100050570
Wyoming	125360300

State of Florida
Department of State

I certify from the records of this office that US MED, LLC is a limited liability company organized under the laws of the State of Florida, filed on August 10, 2015, effective February 19, 1999.

The document number of this limited liability company is L15000134714.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on April 25, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifteenth day of June, 2021

Secretary of State

Tracking Number: 8426049219CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 3/3/2021

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

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

PRODUCER
Arthur J. Gallagher Risk Management Services, Inc.
9155 S Dadeland Blvd Suite 1112
Miami FL 33156

CONTACT NAME:
PHONE (A/C, No, Ext): 305-592-6080 | FAX (A/C, No): 305-592-4049
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Arch Specialty Insurance Company	21199
INSURER B: American Zurich Insurance Company	40142
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED
US MED, LLC
1480 NW 79th Avenue
Miami, FL 33126

UNITSTA-31

COVERAGES **CERTIFICATE NUMBER:** 753923701 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 1,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			BAP 0184650-06	2/23/2021	2/23/2022	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY ☐ X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			FLP005820705	2/23/2021	2/23/2022	EACH OCCURRENCE	$ 2,000,000
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$ 2,000,000
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC 0233413-05	2/23/2021	2/23/2022	X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Misc Med Prof Prof Liab._Claims Made			FLP005820705	2/23/2021	2/23/2022	Occurence Aggregate	$1,000,000 $3,000,000

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

CERTIFICATE HOLDER

US MED, LLC
1480 NW 79th Ave
Miami FL 33126

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

US MED, LLC

List of Owners/Officers/Directors

Name	Title	Address
Timothy Cady	President	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Mark Howard	CEO	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Jeff Abramoff	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
Kurt Hilzinger	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
John Weber	Director	2544 Campbell Place, Ste. 150 Carlsbad, CA 92009
US Med Acquisition, Inc.	100% Owner	8260 NW 27TH ST STE 401 Doral, FL 33122

1480 NW 79TH Ave, Miami, FL 33126
Phone: 877-345-5813 | Fax: 305-455-3587
Email: Licensing@usmed.com

June 15, 2021

Via FedEx

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

RE: US MED, LLC - License # MP00897

Dear Sir or Madam:

This letter provides notice of a change in the indirect ownership of US MED, LLC which holds the above referenced permit. Effective July 21, 2021, US MED Buyer, inc. will become the sole shareholder of US MED Acquisition, Inc. the facility's parent company. The enclosed organizational chart shows the ownership structure after the transaction. As stated above, this change took place two levels above the operating entity.

Importantly US MED, LLC continues to be the direct owner of the facility. There has been a change in officer's, but the facility will:

- Retain the same EIN
- Retain the same name
- Retain the same location
- Retain the same pharmacist in charge
- Retain the same employees
- Retain the same Home State Pharmacy Permit Number

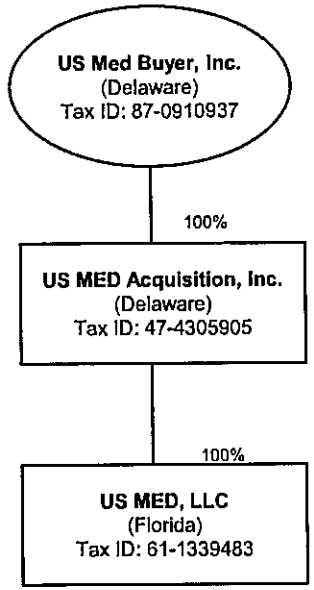
Please let us know if you require any additional information at licensing@usmed.com.

Sincerely,

Mary Ellen Conway

Mary Ellen Conway
Chief Compliance Officer

US MED, LLC – Post-Closing Structure Chart



NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: US MED, LLC MDEG License # (if applicable): _____

Physical Address: 1480 NW 79TH AVE

City: Miami State: FL Zip: 33126

Mailing Address (if different from physical address): 8260 NW 27TH ST STE #403

City: Doral State: FL Zip: 33122

Telephone: 800-787-6331 Website: www.usmed.com

Licensing Company Email: Licensing@usmed.com

Section 2: Personal Information

First: Mary Ellen Middle: _____ Last: Conway

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

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

Mailing Address: [redacted] NW 27TH ST STE [redacted]

City: Doral State: FL Zip: 33122

Telephone: [redacted] Email: Licensing@usmed.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Georgetown University - School of Nursing		08/77-05/81	
Address	City	State	Zip
3700 O St NW	Washington	DC	20057
Diploma/Degree obtained, if any			
Bachelor of Science - Nursing			

School Name		From - To (MM/YY – MM/YY)	
Immaculata College Prep		09/73-05/77	
Address	City	State	Zip
	Washington	DC	20015
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/07-present	[redacted] Haviland Drive	Bethesda	MD	20817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
US MED, LLC			09/16-present	
Business Address		**City**	**State**	**Zip**
8260 NW 27TH ST STE #403		Doral	FL	33122
Phone	**Title**		**Number of Employed Hours**	
877-345-5813	Chief Compliance Officer		40 hours a week	
Description of Duties				
Chief Compliance Officer for DME and Pharmacy operations				

Business Name			From - To (MM/YY – MM/YY)	
Capital Healthcare Group, LLC			09/99-Present	
Business Address		**City**	**State**	**Zip**
6305 Haviland Drive		Bethesda	MD	20817
Phone	**Title**		**Number of Employed Hours**	
301-896-0193	Consultant, President		20 hours a week	
Description of Duties				
Consultant				

Business Name			From - To (MM/YY – MM/YY)	
Thompson Powers, LLC			09/98-09/99	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Director of Post Acute Services		40 hours a week	
Description of Duties				
Consultant				

Business Name			From - To (MM/YY – MM/YY)	
Personal Touch Home Care			07/93-09/98	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Administrator/Regional Director		40 hours a week	
Description of Duties				
Field nurse and administrator				

Business Name			From - To (MM/YY – MM/YY)	
Staff Builders Home Health Care			12/90-07/93	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	Regional Director of Pediatrics		40 hours a week	
Description of Duties				
Field nurse and administrator				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Boston Children's Hospital		09/81-08/83	
Business Address	City	State	Zip
	Boston	MA	
Phone	Title	Number of Employed Hours	
	Staff Nurse	40 hours a week	
Description of Duties			
Full time staff nurse on pediatric medical floor			

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-23-21
Date

I, Mary Ellen Conway, **certify that as the MDEG Administrator for**

US MED, LLC,

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

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

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

Mary Ellen Conway
Print Name (First, Last)

Mary Ellen Conway
Original Signature (electronic, copies or stamps not accepted)

6-23-21
Date

Board Use Only	Date Received:

4GG

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change
(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership – Pages 1,2,3,6
☒ Non Publicly Traded Corporation – Pages 1,2,3,5 ☐ Sole Owner – Pages 1,2,3,7
Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: Visible Supply Chain Management

Physical Address: 6077 West Wells Park Rd, West Jordan, UT 84081
(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 5160 Wiley Post Way

City: Salt Lake City State: Utah Zip Code: 84116

Telephone: 877-728-5328 Fax: _____

E-mail: dave.collings@visiblescm.com Website: www.visiblescm.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 8 to 5 Tue: 8 to 5 Wed: 8 to 5 Thu: 8 to 5 Fri: 8 to 5 Sat: ____ to ____ Sun: ____ to ____ Holidays: ____ to ____

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: David Collings

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☐ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: Contact Lenses

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name: David Collings Telephone: 435-319-4070

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

D A C. G

Original Signature of Person Authorized to Submit Application, no copies or stamps

David Collings

Print Name of Authorized Person

April 12, 2021

Date

Board Use Only	Received:_____	Amount: 500 Check # 00159

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Utah

Parent Company if any: VSCM Holdings, LLC

Corporation Name: Visible Supply Chain Management, LLC

Mailing Address: 5160 Wiley Post Way

City: Salt Lake City State: UT Zip: 84116

Telephone: 877-728-5328 Fax:

Contact Person: Dave Collings

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) VSCM Holdings, LLC (Name) 5160 Wiley Post Way, Salt Lake City, UT 84116 (Address)

b) _____ (Name) _____ (Address)

c) _____ (Name) _____ (Address)

d) _____ (Name) _____ (Address)

2) Provide the number of shares issued by the corporation. 100,000

3) What was the price paid per share? $100,000.00

4) What date did the corporation actually receive the cash assets? March 15, 2019

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non-publicly traded corporation

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

EXHIBIT A

UNIT REGISTER OF VISIBLE SUPPLY CHAIN MANAGEMENT, LLC

NAME, INITIAL CAPITAL CONTRIBUTION, AND

UNITS OF THE MEMBERS

Name	Units	Total Percentage Interest
VSCM Holdings, LLC	100,000	100%
Total	**100,000**	**100%**

VSCMHOL-01 CBRIMHALL

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 6/11/2020

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

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

PRODUCER	CONTACT NAME: Chris Brimhall
Diversified Insurance Group 136 E. South Temple, Suite 2300 Salt Lake City, UT 84111	PHONE (A/C, No, Ext): (801) 325-5033 FAX (A/C, No): E-MAIL ADDRESS: cbrimhall@diversifiedinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hartford Fire Insurance Co	19682
INSURER B : Hartford Insurance Group	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED

VSCM Holdings, LLC
5160 W. Wiley Post Way
Salt Lake City, UT 84116

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT X LOC OTHER:			34UUNVT2471	6/1/2020	6/1/2021	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ 2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS HIRED AUTOS ONLY NON-OWNED AUTOS ONLY			34UUNVT2471	6/1/2020	6/1/2021	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			34RHUZT3021	6/1/2020	6/1/2021	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		34WEAF9VLD	6/1/2020	6/1/2021	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
A	Auto Physical Damage			34UUNVT2471	6/1/2020	6/1/2021	Comp/Coll Deductible	1,000

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

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Chris Brimhall

© 1988-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 6-3-21

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Contact Lens Distribution (Visible Supply Chain Management)
Nature of MDEG

Visible SCM 6077 Wells Park Rd, West Jordan, UT 84081
Name and Address of Business for Which MDEG Administrator Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Bush (Last Name) | William (First Name) | Davis (Middle Name)

Bill

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] East Baycrest Dr Saratoga Springs, UT 84045

Present Residence Address-Street or RFD | City | State/Zip

Visible SCM 6077 Wills Park Rd West Jordan, UT 84081

Present Business Address | City | State/Zip

Sr Director of Fulfillment Ops Dates 9-21-20 to present

Present Position with the MDEG

Phone: [redacted] Fax:

Email address: bill.bush@visiblescm.com

[redacted]
Date of Birth

San Mateo, San Mateo, CA
Place of Birth (City, County, State)

62
Age

[redacted]
Social Security Number or ITIN

M
Sex

Brn
Color of Eyes

Brn
Color of Hair

165
Weight

5'-11"
Height

Scars, tattoos or distinguishing marks and/or characteristics

NA

Are you a citizen of the United States? (Yes) No

If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
9-21-20 to present	Visible SCM 6077 West Park Rd, West Jordan, UT	1,280
Title	**Description of Duties**	**Name of Supervisor**
Sr Director of Fulfillment	Manage Operations Client Fulfillment	Rod White
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
1-95 to 8-20	Walgreens 104 Wilmot, Deerfield, IL 60015	51,000
Title	Description of Duties	Name of Supervisor
Sr Director Supply Chain	Manage Distribution Operations	Andy Kettlewell
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor
Month and Year	Name/ Address of Employer/Business	No of Employed Hours
Title	Description of Duties	Name of Supervisor

I have (I have not) been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have (I have not) been charged, arrested or convicted of a felony or misdemeanor.
2. I have (I have not) been the subject of an administrative action whether completed or pending.
3. I have (I have not) had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information **and** provide a written explanation and/or documents.

a) Board Administrative Action: State:_____
b)
Date: _____

Case Number: _____

c) Criminal Action: State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4 . Will you be actively involved in and aware of the daily operation of the MDEG? (Yes) No

5 .Will you be employed fulltime with the MDEG? (Yes) No

6 .Will you be present at the site of the MDEG during its normal operating hours? (Yes) No

If you answer No to questions 4, 5 or 6 please provide a written letter of explanation.

.....

.....

.....

.....

.....

ATTACH PHOTOGRAPH TAKEN WITHIN LAST 30 DAYS HERE



Date of photograph 6-3-21

I, William Bush, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

WilDB

Original Signature of Applicant

Utah Department of Commerce
Division of Corporations & Commercial Code
160 East 300 South, 2nd Floor, PO Box 146705
Salt Lake City, UT 84114-6705
Service Center: (801) 530-4849
Toll Free: (877) 526-3994 Utah Residents
Fax: (801) 530-6438
Web Site: http://www.commerce.utah.gov

03/19/2021
10321930-016003192021-2628384

CERTIFICATE OF EXISTENCE

Registration Number:	10321930-0160
Business Name:	VISIBLE SUPPLY CHAIN MANAGEMENT, LLC
Registered Date:	March 29, 2017
Entity Type:	LLC - Domestic
Status:	Current

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

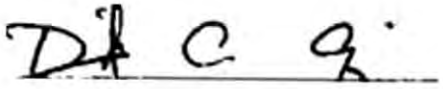
L. Veillette

Leigh Veillette
Director
Division of Corporations and Commercial Code

To Whom it may Concern:

Visible Supply Chain Management agrees to comply with all Nevada laws and rules relating to the sale and/or dispensing of contact lenses.

David Collings



Director or Transportation Compliance

435-319-4070

Visible Supply Chain Management Operating locations:

Fulfillment Centers where contact lenses will be distributed from:

1. 6077 West Wells Park Rd.

   West Jordan, Utah 84081

Corporate Officers:

- Jared Starling (CEO)
- Casey Adams (President)
- Gent White (CFO)
- Kurt Flygare (CRO)
- Jeff Broadhead (CTO)
- Brian Bowers (COO)
- John Dudash (CMO)

4HH

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**Check only**) Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change

(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5
☒ Partnership - Pages 1,2,3,6
☐ Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

FACILITY INFORMATION

Facility Name: NDC Homecare LLC dba Wolf Medical

Physical Address: 13951 Northwest 8th St Sunrise FL 33325

(This must be a business address, we cannot issue a license to a home address)

Mailing Address: 402 BNA Drive Ste 500

City: Nashville State: TN Zip Code: 37217

Telephone: 6153664225 Fax: none

E-mail: tbeasley@ndc-inc.com Website: www.wolfmed.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 7:30 to 4:30 Tue: 7:30 to 4:30 Wed: 7:30 to 4:30 Thu: 7:30 to 4:30 Fri: 7:30 to 4:30 Sat: none to Sun: none to Holidays: none to

MDEG ADMINISTRATOR INFORMATION: Person in charge on a daily basis

Name: Johana Salazar

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☒ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact.

Name:_____ Telephone: _____

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

none

We only drop ship to patients no other contact

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☒ No ☐

Are any of the owners health professionals? If yes, please list name.

- Practitioner Name: _____
- Advanced Practitioner of Nursing Name: _____
- Physician's Assistant Name: _____
- Physical Therapist Name: _____
- Occupational Therapist Name: _____
- Registered Nurse Name: _____
- Respiratory Therapist Name: _____

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

1) Has the corporation, any owner(s), shareholder(s) or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

This page must be submitted for all types of ownership.

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Tammy Beasley
Print Name of Authorized Person

1/20/2021
Date

Board Use Only	Received:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE MDEG LICENSE

OWNERSHIP IS A PARTNERSHIP General_____ Limited X

Partnership Name: NDC Intermediate Holdings LLC

Mailing Address: 40 BNA Drive Ste 500

City: Nashville State: TN Zip: 37217

Telephone: 615 366 3330 Fax: none

Contact Person: Tammy Beasley

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
NDC Intermediate Holdings LLC	L	100%

List names of 4 largest partners and percentage of ownership:

Name: see above %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/24/2020

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

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

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A: Medmarc Casualty Insurance Company — 22241
INSURED NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217	INSURER B:
	INSURER C:
	INSURER D:
	INSURER E:
	INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W18797041 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
	COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$
	☐ CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
							MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$
	☐ OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	☐ ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products & Completed Operations			20TN380008	09/30/2020	09/30/2021	See below	

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

SEE ATTACHED

CERTIFICATE HOLDER

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

CANCELLATION

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

AUTHORIZED REPRESENTATIVE



© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359

AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Willis Towers Watson Southeast, Inc.	NDC Homecare, LLC BNA Corporate Center 402 BNA Drive Suite 500 Nashville, TN 37217
POLICY NUMBER See Page 1	
CARRIER: See Page 1 / NAIC CODE: See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Claims Made
$5,000,000 Each Occurrence
$5,000,000 Prod/Comp Operations Aggregate
$10,000 Medical Expense (any one person)
$25,000 Deductible per Occurrence

ACORD 101 (2008/01)

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 20377599 BATCH: 1896359 CERT: W18797041

Yes answers

07/2007 Mark Seitz President and CEO plead guilty to a misdemeanor " reckless endangerment" Nashville TN

inted on 10/2/2007 at 12:15:09

General Sessions Disposition

arrant #: GS335150

] I hereby waive my right to counsel.

Motion for Waiver of Right to Counsel

Having been heretofore advised of my right to counsel pursuant to the authority granted by TCA 40-14-103, the 6th and 14th Amendments to the United States Constitution, Article 1, Section 9 of the Tennessee Constitution, I hereby move to waive my right to counsel which motion of the Court is pleased to grant.

The defendant make oath in due form that he has been advised by the Court of the constitutional right of every defendant to be represented by counsel and to have one appointed by the Court if the defendant cannot afford one, pursuant to TCA 40-14-103.

This motion is concurred by the Assistant District Attorney General.

CRIMINAL COURT OF DAVIDSON COUNTY

Assistant Attorney General Interpreter Defendant Mark Tyler Seitz

Strong

SWORN to and subscribed before me this _____ day of _____, _____. _____ Deputy Clerk

The defendant Mark Tyler Seitz pleads [X] guilty [ ] not guilty to the offense of

39-13-103 Reckless Endangerment- No Weapon A Misdemeanor

and waives his right to be tried only by indictment or presentment preferred by a Grand Jury, and likewise waives trial by a jury of his peers.

Defendant Mark Tyler Seitz Attorney:

Whereupon, said defendant appeared before the Judge of the Court of General Sessions of Davidson County, Tennessee, on said charge was informed by said Judge of the offense with which he was charged, of his right to make a statement in reference to the charge or his right to waive such statement, and being asked by said Judge whether he desired to plead guilty, or not guilty, said defendant waived the right to a hearing of this case by a Grand Jury and the right to be put on trial by indictment or presentment and waived the right to a trial by a jury, and then entered a plea of [X] guilty [ ] not guilty to said charge and requested that this case be heard and determined by this court and said judge upon the warrant without indictment or jury and upon said plea the Court having heard the evidence produced by the State and Defendant and argument of counsel for the defendant, find the defendant guilty of the offense charged in the warrant and hereby orders and adjudges the defendant pay a fine of $350.00 and all the costs of this cause, and that in addition to said fine and costs said defendant be committed to and confined in said workhouse of Davidson County for a period of :

DISPOSITION

[X] Pled Guilty [ ] Found Guilty [ ] Not Guilty [ ] 40-35-313 [ ] 40-15-105

[ ] Dismissed [ ] Dismissed on Costs [ ] Dismissed ROS [ ] Dismissed, Cost to Pros

[ ] Nolled [ ] Nolo Contendere [ ] Retired on Costs [ ] Retired

SENTENCE

Years 11 Months 29 Days Hours @ % [ ] Suspended PROB TERM

Suspend All But 5 DAYS @ % [ ] Day for Day [ ] Hour for Hour

% before work release [ ] No Work Default [ ] No Early Release

Consecutive To: Concurrent With:

Time Served Credit: Months 0 Days 3 Hours

Special Conditions :

9-24-08

PROBATION

[X] Supervised [ ] Unsupervised [ ] Community Corrections Years 11 Months 29 Days

$350.00 Fine

Special Conditions :

I hereby certify that this is a true and exact copy of the original

Court Mandates

Alcohol Safety Course 0 Years 0 Months 0 Days 0 Hours 0 Weekends

This 12th day of Oct, 2018

CRIMINAL COURT CLERK

By: D.C.

Unpaid Community Service : [ ] Yes [ ] No Hours Days Weeks Months

Restitution Total Amount: Amount Per Month: Recipient:

Address:

Judge Angelita Blackshear Dalton III Div 10/02/2007 Date

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NDC HOMECARE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NDC HOMECARE, LLC" WAS FORMED ON THE SECOND DAY OF MARCH, A.D. 2017.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6333287 8300

SR# 20210367024

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202460786

Date: 02-08-21

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and **non-transferable checks only)**

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

See Attachment B

☐ New Wholesaler or ☑ Ownership Change (Provide current license number if making changes: WH 02554
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

- ☐ Publicly Traded Corporation – Pages 1,2,3,4
- ☐ Partnership - Pages 1,2,3,7,8
- ☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
- ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: AMAG Pharmaceuticals, Inc.

Physical Address: 1100 Winter Street

City: Waltham State: MA Zip Code: 02451

Telephone Number: 617-498-3300 Fax Number: 617-499-3361

Toll Free Number: N/A

E-mail: jvittiglio@amagpharma.com Website: www.amagpharma.com

Facility Manager: Joseph Vittiglio

Professional qualifications and experience of facility manager: See Attachment C

Types of licensed outlets or authorized persons firm will serve:

- ☑ Pharmacies
- ☐ Practitioners
- ☑ Hospitals
- ☑ Wholesalers
- ☐ Other:

Type of Products to be handled or wholesaled by firm:

- ☑ Legend Pharmaceuticals, Supplies or Devices
- ☐ Hypodermic Devices
- ☐ Poisons or Chemicals
- ☐ Veterinary Legend Drugs
- ☐ Controlled Substances (include copy of DEA)
- ☐ Other:

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)
See Attachment D

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment E
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Joseph Vittiglio
Print Name of Authorized Person

11-11-2020
Date

Board Use Only	Date Processed:_____	Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Covis Holdings US, Inc.

Mailing Address: 1100 Winter Street

City: Waltham State: MA Zip: 02451

Telephone: 617-498-3300 Fax: 617-499-3361

Contact Person: Joseph Vittiglio

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Covis Holdings US, Inc. 251 Little Falls Drive, Wilmington, DE 19808
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. Covis holds 100 shares of the applicant

3) What was the price paid per share? Cpvos acquired applicant through a merger for an aggregate of approximately $498 million.

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment F

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment G

Attachment A

Resident State License and Verification

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000303	03/27/2021	03/27/2022	Virtual Drug Manufacturers

ISSUED TO

AMAG PHARMACEUTICALS, INC.
1100 WINTER STREET
WALTHAM, MA 02451
ATTN: JOSEPH VITTIGLIO ESQ. GENERAL COUNSEL, QUALITY AND CORPORATE SECRETARY

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

RENEWAL

842071

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000303	03/27/2021	03/27/2022	Virtual Drug Manufacturers

ISSUED TO

AMAG PHARMACEUTICALS, INC.
1100 WINTER STREET
WALTHAM, MA 02451
ATTN: JOSEPH VITTIGLIO ESQ. GENERAL COUNSEL, QUALITY AND CORPORATE SECRETARY

RENEWAL

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000303	03/27/2020	03/27/2021	Virtual Drug Manufacturers

ISSUED TO

AMAG PHARMACEUTICALS, INC.
1100 WINTER STREET
WALTHAM, MA 02451
ATTN: JOSEPH VITTIGLIO ESQ. GENERAL COUNSEL, QUALITY AND CORPORATE SECRETARY

COMMISSIONER OF PUBLIC HEALTH

835009

RECIPIENT'S COPY

RENEWAL

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000303	03/27/2020	03/27/2021	Virtual Drug Manufacturers

ISSUED TO

AMAG PHARMACEUTICALS, INC.
1100 WINTER STREET
WALTHAM, MA 02451
ATTN: JOSEPH VITTIGLIO ESQ. GENERAL COUNSEL, QUALITY AND CORPORATE SECRETARY

RENEWAL

Attachment B

Regarding the Ownership Change

On or around November 16, 2020, AMAG Pharmaceuticals, Inc. "AMAG" will undergo a change in ownership and will become a wholly-owned subsidiary of Covis Holdings US, Inc. following the closing. Covis Holdings US, Inc. is a wholly-owned subsidiary of Covis Group S.à r.l. AMAG will continue to operate as it did prior to the closing and there will be no change to AMAG's federal identification number as a result of the transaction. Legal documentation of the ownership change will be provided when available.

Theresa D. Ankamah, PharmD, RPh

[redacted] Grand Ridge Court ◆ Gahanna, OH 43230

Cell: [redacted] ◆ Home: [redacted] ◆ Email: tankamah@covispharma.com

Experienced Executive Medical Affairs leader with proven results in Publication Planning, Scientific Communications, Field Medical Affairs, Clinical Operations, and Multiple launch products in Cardiovascular and Metabolic therapeutic areas as well as Hepatology, Neurology, Hematology/Oncology, with in-depth knowledge of the pharmaceutical industry's regulatory environment, medical affairs functions, and clinical trial expertise on a national and global level. An innovative leader, who has successfully developed, championed others, and implemented projects to drive competitive advantage and impact business results and goals.

Demonstrated effective communication and problem-solving skills, necessary to work cross functionally (teamwork) with individuals/teams at all levels within the organization consistently.

Collaborative leader within Medical Affairs with extensive experience in successful employee engagement and development, thought leader management, commercial liaison, project leadership, medical information, Medical Science Liaison roles and leadership. Demonstrated proven management experience in leading high performing teams, strategically and operationally.

PROFESSIONAL EXPERIENCE

2020-Present **Covis Pharma/AM6 Pharmaceuticals** **Waltham, MA**

Vice President, Medical Affairs

- Define and develop the US Medical Strategy team in the creation of appropriate processes, standards, and policies
- Accountable for the overall function and governance of MA, ensuring alignment with the Commercial organization and collaborating with their respective leaders
- Accountable for the strategy and tactic development for MA activities and Key Opinion Leader (KOL) advocacy plans to build and maintain critical relationships and knowledge management.
- Provide inspirational leadership by creating an environment of mutual respect and shared goals, clear responsibilities, talent development/engagement/retention plans, and continuous improvement, growth mindset
- Overall responsibility for ensuring appropriate resources are available to deliver the MA strategies and tactics
- Oversee team development, coaching and support of all direct and indirect reports to ensure competency to develop and execute the MA strategy, as well as professional development opportunities for the team
- Demonstrate the clinical value of our products by providing input and effectively leveraging health economics, observation research and Real-World Data (RWD) to meet the needs of payers and treatment guidelines committee members
- Provide support for patient advocacy activities working closely with the commercial organization
- Direct involvement in implementation of plans that will be executed through multi-modal medical education channels, including publications, presentations, congresses, advisory boards, CME, speaker bureaus and other channels in support of our products
- Development and implementation of detailed scientific Publication Plans
- Build and lead Medical Science Liaison (MSL) organization responsible for presenting medical information regarding company products to physicians and other healthcare professionals
- Strategy and oversight for the development of a supportive Investigator Initiated Study program
- Demonstrate functional leadership through scientific expertise and in-depth understanding (scientific and medical) of relevant disease states, products, competitors, marketplace, related medical areas and regulatory guidelines.

- Ensure that all interactions and activities adhere to corporate and healthcare compliance guidance in all activities, including those related to clinical trials, scientific interactions with internal and external groups, and responses to unsolicited requests for medical/scientific information

2020-2020 **AMAG Pharmaceuticals** **Waltham, MA**
Executive Director, Medical Affairs, Hematology-Oncology

- Lead Medical Affairs responsibility for pipeline product and launch preparation
- Review and approval of Investigator Initiated Studies, Medical Education, and Grants
- Responsibility for the overall Medical Affairs strategy
- Medical Lead for ongoing and future Phase IV studies, including clinical trials, retrospective chart reviews and Health Economics and Outcomes Research
- Establish and maintain cross functional relationships with Clinical Development, Commercial, Regulatory and Legal colleagues
- Review publications abstracts, medical information letters, and any externally facing content for medical accuracy
- Plan, prepare, and lead scientific advisory board meeting and content development
- Oversight and responsibility for Field Medical Affairs

2018-2020 **AMAG Pharmaceuticals** **Waltham, MA**
Senior Director, Field Medical Affairs Hematology Oncology

- Define strategic direction for Field Medical Affairs and ensure alignment with corporate and commercial initiatives
- Develop Field Medical Affairs strategic plans for external engagement
- Member of the Product and Asset team meetings to create medical strategic plan for AMAG products
- Lead Medical Affairs responsibility for Pipeline product and launch preparation
- Developed resource planning leading to launch of future pipeline
- Lead the development of CRM creation for Field Medical Affairs
- Direct leadership responsibility for the AMAG Medical Science Liaison team including recruiting, hiring, and retaining qualified candidates
- Clinical and scientific support of activities including internal clinical input and training to commercial functions.
- Provide regular field updates and insight to internal stakeholders in home office
- Ensure highest scientific standard and expertise across the MSL team in order to establish strong peer-to- peer collaborations and professional relationships
- Development, execution and maintenance of MSL SOP's; develops metrics to track success of MSL team
- Ensure the MSL team is deployed appropriately to support the field commercial organization
- Manage administrative aspects of the team including review and approval of expense reports, timesheets, and database entries.
- Provide appropriate mentoring and coaching to direct reports with respect to technical skills, business acumen/planning, and effective regional management.

2016-2018 **Boehringer Ingelheim Pharmaceuticals, Inc** **Ridgefield, CT**
Senior Associate Director, Field Based Medicine CardioMetabolic

- Lead and direct a team of 30 Cardiometabolic MSLs
- Lead strategic initiatives for the Metabolic team
- Mentor, train, and coach newly hired MSL managers/directors within Field Based Medicine
- Lead all Clinical Operations initiatives for Metabolism, ranging from site feasibility, identification of sites, and investigator meetings
- Drive and provide direction on how insights from HCPs are communicated internally and aligning areas of interest for the organization
- Pivotal role in roll out of global trials to Field Based Medicine

2012-2016 **Boehringer Ingelheim Pharmaceuticals, Inc** **Ridgefield, CT**
Senior Associate Director, Field Based Medicine Metabolic

- Strategically lead team of 10 Medical Science Liaisons (MSLs), while encouraging smart risks, innovation, and empowering MSLs within their territories
- Oversee compliance with an annual travel budget for 20 Medical Science Liaison (MSL) teams in Metabolic Therapeutic Area (TA) in partnership with TA Director and Finance

- Developed process for establishing therapeutic area key events, field team (MSLs) customer-facing activities, capacity allocations and target populations to project Medical Plans of Action (MPoA) for all priority brands.
- Co-authored guideline outlining process for gathering and analyzing strategic insights, developing MPoA for therapeutic area key-life-cycle events, and deploying MSLs with specific accountabilities to measure performance against plan.
- Created MEDImpact data output brand presentations to capture real-world data, drive strategic decision-making, and identify cross-functional and actionable opportunities
- Oversee MSL therapeutic area expertise and capability training
- Participate on key global and regional strategic teams such as Global Brand teams, Global Medical Affairs teams and regional strategic teams, as appropriate, to align field activities and initiatives to meet scientific and business objectives.
- Ensure the MSL team is appropriately trained and resources are made available for success in the field.
- Ensures cross functional meetings for various brands are completed to promote collaboration between teams.
- Partly responsible to the development of product dossier and review from Medical perspective
- Oversee planning and deployment of MSLs at national and international congresses in alignment with budget and resources.
- Analyze clinical and market trends to develop key supporting strategies to meet business objectives.
- Actively oversee the recruitment and retention of MSLs.
- Manage financial and budget accountabilities for direct reports.
- Maintain in depth understanding of disease state, competitors, marketplace, and products
- Strategic involvement in goal setting for MSLs
- Develop and deliver scientific presentations to Marketing, Sales, CDMA, and FBM
- Cross functional alignment with Commercial (Managed Markets, brand managers, Medical Marketing Liaisons)
- Partner with Global colleagues to identify opportunities for MSLs, such as attendance at global meetings and coverage of Medical Information booths
- Identify, submit, and request approval of scientific resources for team use
- Review and endorse Scientific Experts(SCE) identification for regional MSLs
- Act as therapeutic area medical expert with Regulatory, Legal, Marketing, and Sales
- Review and approve all regional MSL scientific exchanges
- Coordinate communication of team scientific insights from MSLs to internal Medical and Marketing teams
- Monitors regional MSL activity proactively to ensure compliance controls for the MSL team is followed.
- Ensure adherence to FBM policies, procedures, and guidance
- Coach, develop, motivate, manage and monitor performance of a staff of 10 MSLs.
- Engage employees in development planning discussions on a regular basis to ensure professional development.
- Lead and manage a regional MSL team through the implementation of activities that support the TA Scientific Objectives (SOs).
- In collaboration with the Director & VP, oversee team POA plan development and execution
- Assure that Medical Science Liaison team meets or exceeds metric, compliance, and administrative expectations on an ongoing basis.

2010-2012 **Boehringer Ingelheim Pharmaceuticals, Inc** **Ridgefield, CT**
Associate Director, Field Based Medicine, Cardiometabolic Diseases

- Active participation in recruiting process for Field-Based Medical Team (FBMT) personnel, including identification of coverage gaps in field and facilitation of new hire training process.
- Responsible for building the diabetes team at BI in 2010
- Built and recruited Metabolic MSL team in anticipation for approval of Linagliptin in 2011
- At medical congresses, oversee deployment of MSLs to meet business needs.
- In collaboration with the SAD, oversee team POA plan development and execution
- Assure that Medical Science Liaison team meets or exceeds metric, compliance, and administrative expectations on an ongoing basis.

- Host Monthly team meetings/teleconferences to ensure accurate dissemination of information.

2009-2010 **Boehringer Ingelheim Pharmaceuticals, Inc** **Ridgefield, CT**
Senior Medical Science Liaison, Cardiovascular

- Serve as Compliance Liaison for the Cardiometabolic Team
- In concert with key partners, update pertinent information for Field Deployment Workshop
- Function as the Cardiovascular Team speaker bureau liaison
- Develop and maintain relationships with Key Opinion and Thought Leaders (KOL's) in therapeutic area.
- Conduct field visits with Medical Science Liaison's when commissioned by Field-based Medical Affairs Management
- Provide unsolicited presentations to managed markets accounts, state and federal accounts, and Medicaid
- Part of the team that created and facilitated GLI compliance training at December 2009 POA
- Facilitate the mentoring program for Cardiovascular Team
- Function as a key clinical and scientific resource to KOL's
- Facilitate speaker training for Pradaxa®, Micardis® and Twynsta®
- Serve as a mentor for multiple new hires on the cardiovascular team during their transition
- Maintain thorough and up-to-date knowledge of disease state, clinical information, therapeutic options and product data within therapeutic area

2006-2009 **Boehringer Ingelheim Pharmaceuticals, Inc** **Ridgefield, CT**
Manager, Regional Medicine

- Developed and maintained relationships with Key Opinion and Thought Leaders (KOL's) in therapeutic area
- Facilitated the mentoring program for Cardiovascular Team
- Functioned as a key clinical and scientific resource to KOL's
- Facilitated speaker training for Micardis® and Aggrenox® via webcast
- Served as a mentor for multiple new hires on the cardiovascular team during their transition
- Maintained thorough and up-to-date knowledge of disease state, clinical information, therapeutic options and product data within therapeutic area
- Developed strategies and tactics to effectively communicate complex scientific information
- Delivered presentations on clinical and scientific data to physicians and other healthcare providers
- Delivered presentations on scientific data to managed markets accounts.
- Attended scientific congresses, conventions and symposia and provide competitive information to leverage the Micardis® and Aggrenox® brands
- Managed expenses and budget responsibly
- Portfolio Management: research, literature searches
- Planned and successfully managed an international scientific congress (European Society of Cardiology)
- Provided training to managed markets regional account managers on Aggrenox® and Micardis®
- Managed the planning and development of agenda for team plan of action meeting

2006 **Daiichi Sankyo Inc** **Parsippany, NJ**
Manager, Medical Affairs (Evoxac and Floxin Otic)

- Developed and maintained a comprehensive and medically accurate product database of medical letters in response to inquiries received from internal and external customers for Evoxac® (cevimeline HCl) and Floxin Otic
- Provided management and training of an off-site call center vendor on Evoxac® (cevimeline HCl) and Sjögren's syndrome
- Provided medical review of promotional pieces, educational materials, and slide presentations in concert with regulatory affairs and legal affairs for Evoxac® (cevimeline HCl)

2005-2006 **Sankyo Pharma** **Parsippany, NJ**
Post Doctoral Pharmaceutical Industry Fellow, Medical Affairs

- Developed and maintained a comprehensive and medically accurate product database of medical letters in response to inquiries received from internal and external customers for Benicar® (olmesartan medoxomil), Benicar HCT® (olmesartan medoxomil-hydrochlorothiazide), and WelChol® (colesevelam HCl).
- Revised and updated clinical dossiers for use by managed healthcare organizations and state PDLs for Benicar® (olmesartan medoxomil), Benicar HCT® (olmesartan medoxomil-hydrochlorothiazide), and WelChol® (colesevelam HCl).
- Assisted in the management and training of an off-site call center vendor on Evoxac® (cevimeline HCl) and Sjögren's syndrome
- Worked with an off-site call center vendor to ensure expectations for internal and external customers were being met
- Provided medical review of promotional pieces, educational materials, and slide presentations in concert with regulatory affairs and legal affairs for Benicar® (olmesartan medoxomil), Benicar HCT® (olmesartan medoxomil-hydrochlorothiazide), and WelChol® (colesevelam HCl)
- Provided scientific input on manuscripts to ensure accuracy for WelChol® (colesevelam HCl)
- Created and presented assigned topics to the Medical Affairs Department
- Shadowed and participated in key opinion leader interactions with Medical Liaisons
- Attended and captured competitive information from national scientific meetings to leverage WelChol® (colesevelam HCl)
- Longitudinal Field-based Medical Liaison Component
  - Interacted with key consultants at national advisory board meeting
  - Participated in a State Medicaid P&T Public Testimony
  - Participated in a Plan of Action (POA) meeting to help address internal customer needs
  - Participated in several Key Opinion Leader Meetings
- Coordinated the recruitment of incoming fellows
- Precept 8 Rutgers University PharmD students on 1-month rotations for Medical Affairs
- Tracked competitive environment and analyzed information that can be leveraged for competitive advantage in hypertension, dsylipidemia, and diabetes for Benicar®(olmesartan medoxomil),Benicar HCT® (olmesartan medoxomil-hydrochlorothiazide), and WelChol®(colesevelam HCl) and the company

2005-2006 **Institute for Pharmaceutical Industry Fellowship** **Piscataway, NJ**
Co-Chair Website Committee

- Responsible for maintaining the integrity of the fellowship website
- Ensure that content stays up-to-date for current and prospective fellow

2007-2010 **CVS Pharmacy** **Columbus, OH**
Staff Pharmacist

- Counseled patients on appropriate use of medical therapy
- Checked and verified prescriptions prior to dispensing
- Provided superior customer service
- Interacted with physicians and other healthcare professionals
- Management of pharmacy personnel
- Performed drug utilization review

2005-2006 **Duane Reade Pharmacy** **New York, NY**
Overnight Clinical Pharmacist

- Counseled patients on appropriate use of medical therapy
- Checked and verified prescriptions prior to dispensing
- Provided superior customer service
- Interacted with physicians and other healthcare professionals
- Management of pharmacy personnel
- Performed drug utilization review

EDUCATION

2005-2006	**Rutger's Pharmaceutical Industry Fellowship** Medical Affairs, Post Doctoral Fellow	**New Brunswick, NJ**
2000-2005	**St. John's University** **College of Pharmacy & Allied Health Professions** ❖ Doctor of Pharmacy, Conferred May 2005	**Jamaica, NY**
1996-2000	**Marymount College of Fordham University** ❖ Bachelors of Science Chemistry & Computer Science, Conferred May 2000	**Tarrytown, NY**

ACADEMIC APPOINTMENT

2014-2018	**University of Connecticut** Adjunct Assistant Professor, Pharmacy Practice School of Pharmacy	**Storrs, CT**
2005-2006	**The State University of New Jersey, Rutgers** Adjunct Assistant Clinical Professor Ernest Mario School of Pharmacy	**Piscataway, NJ**

LICENSURES AND CERTIFICATIONS

2007	Ohio State Registered Pharmacist License
2005	New York State Registered Pharmacist License

PUBLICATION

Kporha T and Anzisi L. "The Value of Pharmaceuticals" Italian-American Pharmacists Society Newsletter Vol. 22(3) Sept/Oct. 2004.

PROFESSIONAL AWARDS

2018	Teamwork/Collaboration Award for the Boehringer Ingelheim-Eli Lilly Alliance
2015	President's Award for MEDImpact Initiative
2009	Most Valuable Peer Recognition Award 2009 for the Cardiometabolic Team, Boehringer Ingelheim
2007	Most Valuable Peer Recognition Award 2007 for the Cardiovascular Team, Boehringer Ingelheim

COMPUTER SKILLS

Windows 95/2000/XP/Win7/Win9, Microsoft Office 365: Word, PowerPoint, Excel, Access, Outlook, FrontPage, Publisher, Programming in C++, Visual Basic, Secure Shell (SSH), Veeva, Komodo Health, SteepRock, Macromedia, Proficient in internet browsers: Google Chrome, and Internet Explorer

Drug Establishments Current Registration Site

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **AMAG**

CSVExcel

Filter: AMAG Ph

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
AMAG Pharmaceuticals, Inc.	3008152278	017511155	MANUFACTURE;	1100 Winter Street, Waltham, Massachusetts (MA) 02451, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Wednesday, Jun 9, 2021

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified
6/9/21
MS

Attachment F

Corporate Officer and Director Information

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451

Officers:

Joseph Vittiglio, Esq.
EVP, Chief Business Officer, General Counsel, Secretary,

Scott Myers
President, Chief Executive Officer

Brian Piekos
EVP, Chief Financial Officer, Treasurer

Directors:

Gino Santini, Chairman
Scott Myers
Davey S. Scoon
John A. Fallon M.D.
James Sulat
Paul Fonteyne
David Johnson
Kathrine O'Brien
Anne M. Phillips, M.D., FRCPC

The corporate officers and directors may be contacted at the above address.

Attachment E

Nature of Business

AMAG Pharmaceuticals, Inc. (AMAG) is a manufacturer of prescription drugs. AMAG utilizes contract manufacturers to produce its product and a licensed third party logistics provider to warehouse and distribute. Accordingly, AMAG does not physically manufacture or distribute any product. Provided below is the contact information for third parties utilized.

Third Party Logistics Provider:

Integrated Commercialization Solutions, Inc. (ICS)
420 International Blvd., Ste 500
Brooks, KY 40109

Contract Manufacturers:

Patheon Manufacturing Services LLC
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
FDA Registration #: 1018495

Antares Pharma, Inc.
100 Princeton South, Suite 300
Ewing, NJ 08628
FDA Registration #: 085369585

Baxter Pharmaceutical Solutions, LLC
926 S Curry Pike
Bloomington, IN 47403
FDA Registration #: 1000115571

Catalent Belgium S.A.
Font Saint Landry 10
Brussels, - 1120, Belgium
FDA Registration #: 3007647000

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMAG PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF MARCH, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

926007 8300

SR# 20210781841

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202640582

Date: 03-03-21

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMAG PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

926007 8300

SR# 20207210308

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203633303

Date: 09-10-20

SWISS RE CORPORATE SOLUTIONS

NORTH AMERICAN SPECIALTY INSURANCE COMPANY
WASHINGTON INTERNATIONAL INSURANCE COMPANY
WESTPORT INSURANCE CORPORATION

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT North American Specialty Insurance Company, a corporation duly organized and existing under laws of the State of New Hampshire, and having its principal office in the City of Overland Park, Kansas and Washington International Insurance Company a corporation organized and existing under the laws of the State of New Hampshire and having its principal office in the City of Overland Park, Kansas, and Westport Insurance Corporation, organized under the laws of the State of Missouri, and having its principal office in the City of Overland Park, Kansas each does hereby make, constitute and appoint:

WILLIAM L. LABBE, JOHN J. FEITELBURG, CATHERINE H. LAWRENCE, LINDA MERENGUELLI, BRAD TAYLOR, ANNE M. HIGGINBOTTOM, BARRY J. HORGAN, ALYSSA R. MICHAEL and JOHN J. ZAWILINISKI JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

ONE HUNDRED TWENTY FIVE MILLION ($125,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of North American Specialty Insurance Company and Washington International Insurance Company at meetings duly called and held on March 24, 2000 and Westport Insurance Corporation by written consent of its Executive Committee dated July 18, 2011.

"RESOLVED, that any two of the President, any Senior Vice President, any Vice President, any Assistant Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Company bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Company; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Company may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Company when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

By _____
Steven P. Anderson, Senior Vice President of Washington International Insurance Company
& Senior Vice President of North American Specialty Insurance Company
& Senior Vice President of Westport Insurance Corporation

By _____
Mike A. Ito, Senior Vice President of Washington International Insurance Company
& Senior Vice President of North American Specialty Insurance Company
& Senior Vice President of Westport Insurance Corporation

IN WITNESS WHEREOF, North American Specialty Insurance Company, Washington International Insurance Company and Westport Insurance Corporation have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 7TH day of FEBRUARY, 20 18.

North American Specialty Insurance Company
Washington International Insurance Company
Westport Insurance Corporation

State of Illinois
County of Cook ss:

On this 7TH day of FEBRUARY, 20 18, before me, a Notary Public personally appeared Steven P. Anderson, Senior Vice President of Washington International Insurance Company and Senior Vice President of North American Specialty Insurance Company and Senior Vice President of Westport Insurance Corporation and Michael A. Ito Senior Vice President of Washington International Insurance Company and Senior Vice President of North American Specialty Insurance Company and Senior Vice President of Westport Insurance Corporation, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
M. KENNY
Notary Public - State of Illinois
My Commission Expires
12/04/2021

M. Kenny, Notary Public

I, Jeffrey Goldberg, the duly elected Vice President and Assistant Secretary of North American Specialty Insurance Company, Washington International Insurance Company and Westport Insurance Corporation do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said North American Specialty Insurance Company, Washington International Insurance Company and Westport Insurance Corporation which is still in full force and effect.

IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 2nd day of December, 2020.

Jeffrey Goldberg, Vice President & Assistant Secretary of Washington International Insurance Company &
North American Specialty Insurance Company & Vice President & Assistant Secretary of Westport Insurance Corporation

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SNN4008269

Application/License No. _____

AMAG PHARMACEUTICALS, INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1100 Winter Street, Waltham, MA 02451 (Address of Applicant/Principal), as PRINCIPAL, and NATIONWIDE MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of OH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Nationwide Plaza, Columbus OH 43216 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 11/6/2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 6th day of November, 20 20.

APPLICANT/PRINCIPAL
AMAG PHARMACEUTICALS, INC

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Paul M Allen

Witness Rachel Fore

Countersigned by:

Christopher P. Troha, Licensed Non-Resident Nevada Agent

1041742

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS THAT:

Nationwide Mutual Insurance Company, an Ohio corporation hereinafter referred to as the "Company" and does hereby make, constitute and appoint: Christopher P. Troha, Susan A. Welsh, Derek J. Elston, Sandra M. Winsted, Christina L. Sandoval, Judith A. Lucky-Eftimov, Sandra M. Nowak, Anna L. Formhals, Ann Mullins, Aerie Walton, Jennifer Williams, Salena Wood, Eric D. Sauer, Bartlomiej Siepierski, Barbara Pannier

each in their individual capacity, its true and lawful attorney-in-fact, with full power and authority to sign, seal, and execute on its behalf any and all bonds and undertakings, and other obligatory instruments of similar nature, in penalties not exceeding the sum of

UNLIMITED

and to bind the Company thereby, as fully and to the same extent as if such instruments were signed by the duly authorized officers of the Company; and all acts of said Attorney pursuant to the authority given are hereby ratified and confirmed.

This power of attorney is made and executed pursuant to and by authority of the following resolution duly adopted by the board of directors of the Company:

"RESOLVED, that the president, or any vice president be, and each hereby is, authorized and empowered to appoint attorneys-in-fact of the Company, and to authorize them to execute and deliver on behalf of the Company any and all bonds, forms, applications, memorandums, undertakings, recognizances, transfers, contracts of indemnity, policies, contracts guaranteeing the fidelity of persons holding positions of public or private trust, and other writings obligatory in nature that the business of the Company may require; and to modify or revoke, with or without cause, any such appointment or authority; provided, however, that the authority granted hereby shall in no way limit the authority of other duly authorized agents to sign and countersign any of said documents on behalf of the Company."

"RESOLVED FURTHER, that such attorneys-in-fact shall have full power and authority to execute and deliver any and all such documents and to bind the Company subject to the terms and limitations of the power of attorney issued to them, and to affix the seal of the Company thereto; provided, however, that said seal shall not be necessary for the validity of any such documents."

This power of attorney is signed and sealed under and by the following bylaws duly adopted by the board of directors of the Company.

Execution of Instruments. Any vice president, any assistant secretary or any assistant treasurer shall have the power and authority to sign or attest all approved documents, instruments, contracts, or other papers in connection with the operation of the business of the company in addition to the chairman of the board, the chief executive officer, president, treasurer or secretary; provided, however, the signature of any of them may be printed, engraved, or stamped on any approved document, contract, instrument, or other papers of the Company.

IN WITNESS WHEREOF, the Company has caused this instrument to be sealed and duly attested by the signature of its officer the 1st day of May, 2017.

Antonio C. Albanese, Vice President of Nationwide Mutual Insurance Company

Nationwide Mutual Insurance Company CORPORATE 1925 SEAL * Ohio * Surety Use Only

ACKNOWLEDGMENT

STATE OF NEW YORK, COUNTY OF NEW YORK: ss
On this 1st day of May, 2017, before me came the above-named officer for the Company aforesaid, to me personally known to be the officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, deposes and says, that he is the officer of the Company aforesaid, that the seal affixed hereto is the corporate seal of said Company, and the said corporate seal and his signature were duly affixed and subscribed to said instrument by the authority and direction of said Company.

BARRY T. BASSIS
Notary Public, State of New York
No. 02BA4656400
Qualified in New York County
Commission Expires April 30, 2019

Notary Public
My Commission Expires
April 30, 2019

CERTIFICATE

I, Laura B. Guy, Assistant Secretary of the Company, do hereby certify that the foregoing is a full, true and correct copy of the original power of attorney issued by the Company; that the resolution included therein is a true and correct transcript from the minutes of the meetings of the boards of directors and the same has not been revoked or amended in any manner; that said Antonio C. Albanese was on the date of the execution of the foregoing power of attorney the duly elected officer of the Company, and the corporate seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority of said board of directors; and the foregoing power of attorney is still in full force and effect.

IN WITNESS WHEREOF, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of said Company this 6th day of November, 2020.

Assistant Secretary

This document is void if VOID appears in the BLUE line on the right, the Nationwide watermark is missing from the center of the page and/or the red consecutive number is missing from the upper right-hand corner. Contact us at 212-329-6900 if this document is void or if you have any questions.

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF COOK

On this 6th day of November, 2020, before me, Bartlomiej Siepierski, a Notary Public, within and for said County and State, personally appeared Derek J. Elston to me personally known to be the Attorney-in-Fact of and for Nationwide Mutual Insurance Company and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

Notary Public in the State of Illinois
County of Cook

OFFICIAL SEAL
BARTLOMIEJ SIEPIERSKI
NOTARY PUBLIC, STATE OF ILLINOIS
COOK COUNTY
MY COMMISSION EXPIRES 09/16/2023

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Avadel CNS Pharmaceuticals, LLC

Physical Address: 16640 Chesterfield Grove Rd, Suite 200

City: Chesterfield State: MO Zip Code: 63005

Telephone Number: 636-449-1830 Fax Number: 636-449-1850

Toll Free Number: N/A

E-mail: license@avadel.com Website: www.avadel.com

Facility Manager: Heather Kruchowski

Professional qualifications and experience of facility manager:
See resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Specialty Distributors and Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☒ Controlled Substances (include copy of DEA)
☐ Other: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Heather Kruchowski
Original Signature of Person Authorized to Submit Application, no copies or stamps

Heather Kruchowski
Print Name of Authorized Person

5 May 2021
Date

Board Use Only	Date Processed: 5/25/2021 ✓	Amount: 500 Check #13365

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: DE

Parent Company if any: Avadel US Holdings, Inc.

Mailing Address: 16640 Chesterfield Grove Rd, Suite 200

City: Chesterfield State: MO Zip: 63005

Telephone: (636) 449-1830 Fax: N/A

Contact Person: Heather Kruchowski

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) See Attached
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. See Attached

3) What was the price paid per share? See Attached

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

State of Missouri

Division of Professional Registration

Licensed Drug Distributor

VALID THROUGH OCTOBER 31, 2021
ORIGINAL CERTIFICATE/LICENSE NO. 2021000490
AVADEL CNS PHARMACEUTICALS LLC
AVADEL CNS PHARMACEUTICALS LLC
HEATHER KRUCHOWSKI, MIC
16640 CHESTERFIELD GROVE RD STE200
CHESTERFIELD MO 63005
USA

AVADEL CNS PHARMACEUTICALS LLC
AVADEL CNS PHARMACEUTICALS LLC
HEATHER KRUCHOWSKI, MIC
16640 CHESTERFIELD GROVE RD STE200
CHESTERFIELD MO 63005
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy
Licensed Drug Distributor

VALID THROUGH OCTOBER 31, 2021
ORIGINAL CERTIFICATE/LICENSE NO. 2021000490
Heather Kruchowski
AVADEL CNS PHARMACEUTICALS LLC
AVADEL CNS PHARMACEUTICALS LLC
HEATHER KRUCHOWSKI, MIC
16640 CHESTERFIELD GROVE RD STE200
CHESTERFIELD MO 63005
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

State Of Delaware

Entity Details

3/17/2021 9:07:41AM

File Number: 7734658 Incorporation Date / Formation Date: 12/4/2019

Entity Name: AVADEL CNS PHARMACEUTICALS, LLC

Entity Kind: Limited Liability Company Entity Type: General

Residency: Domestic State: DELAWARE

Status: Good Standing Status Date: 12/4/2019

Registered Agent Information

Name: CORPORATE CREATIONS NETWORK INC.

Address: 3411 SILVERSIDE ROAD TATNALL BUILDING STE 104

City: WILMINGTON Country:

State: DE Postal Code: 19810

Phone:

Ownership Information

Avadel CNS Pharmaceuticals, LLC ("Avadel CNS") is a limited liability company. Avadel CNS is 100% owned by parent company Avadel US Holdings, Inc ("Avadel US"). Avadel US is 100% owned by Avadel Pharmaceuticals Plc which is a Publicly Traded company on the NASDAQ stock exchange under the symbol AVDL.

Company Information

Avadel CNS Pharmaceuticals, LLC
16640 Chesterfield Grove Rd. #200
Chesterfield, MO 63005
(636) 449-1830
https://www.avadel.com/
license@avadel.com

FEIN: 84-4723949
State of Formation: Delaware
Date Incorporated: 12/4/2019
File Number: 7734658

Officers

Gregory Divis Jr., Chief Executive Officer
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: Less than 5%

Thomas McHugh, Chief Financial Officer
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: Less than 5%

Jerad Seurer, VP, Deputy General Counsel
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: Less than 5%

Designated Representative

Heather Kruchowski, Senior Director, Quality
16640 Chesterfield Grove Rd., Suite 200
Chesterfield, MO 63005
Ownership: Less than 5%

Avadel
Pharmaceuticals

Description of Operations

Avadel CNS Pharmaceuticals, LLC ("Avadel") is a Virtual Manufacturer. Avadel's products are manufactured by a Contract Manufacturer and distributed to Specialty Distributors and Specialty Pharmacies by a 3PL, Eversana Life Sciences, who is licensed to distribute into the state.

Avadel's products are listed as a Schedule III Controlled Substance. As a virtual manufacturer who does not handle pharmaceuticals at any time, either by physically manufacturing or distributing drugs, Avadel is exempt from obtaining a DEA registration. Accordingly, please see the below DEA information for Eversana who will be warehousing and distributing Avadel product.

Contract Manufacturer Information

Avadel CNS uses the following contract manufacturer to produce product:

Recipharm Pessac
11 Avenue Gustave Eiffel Parc Industriel, Bersol 1
Pessac, France 33608
+46 8 602 52 00
FDA Establishment Identification Number: 3011269473

Sharp Corporation (*Repackager*)
7570 Industrial Park Way
Macungie, Pennsylvania 18062
(610) 395-5800
FDA Establishment Identification Number: 3009566827

At no time does Recipharm or Sharp own the product, contract with Avadel's customers, invoice, nor sell an Avadel product.

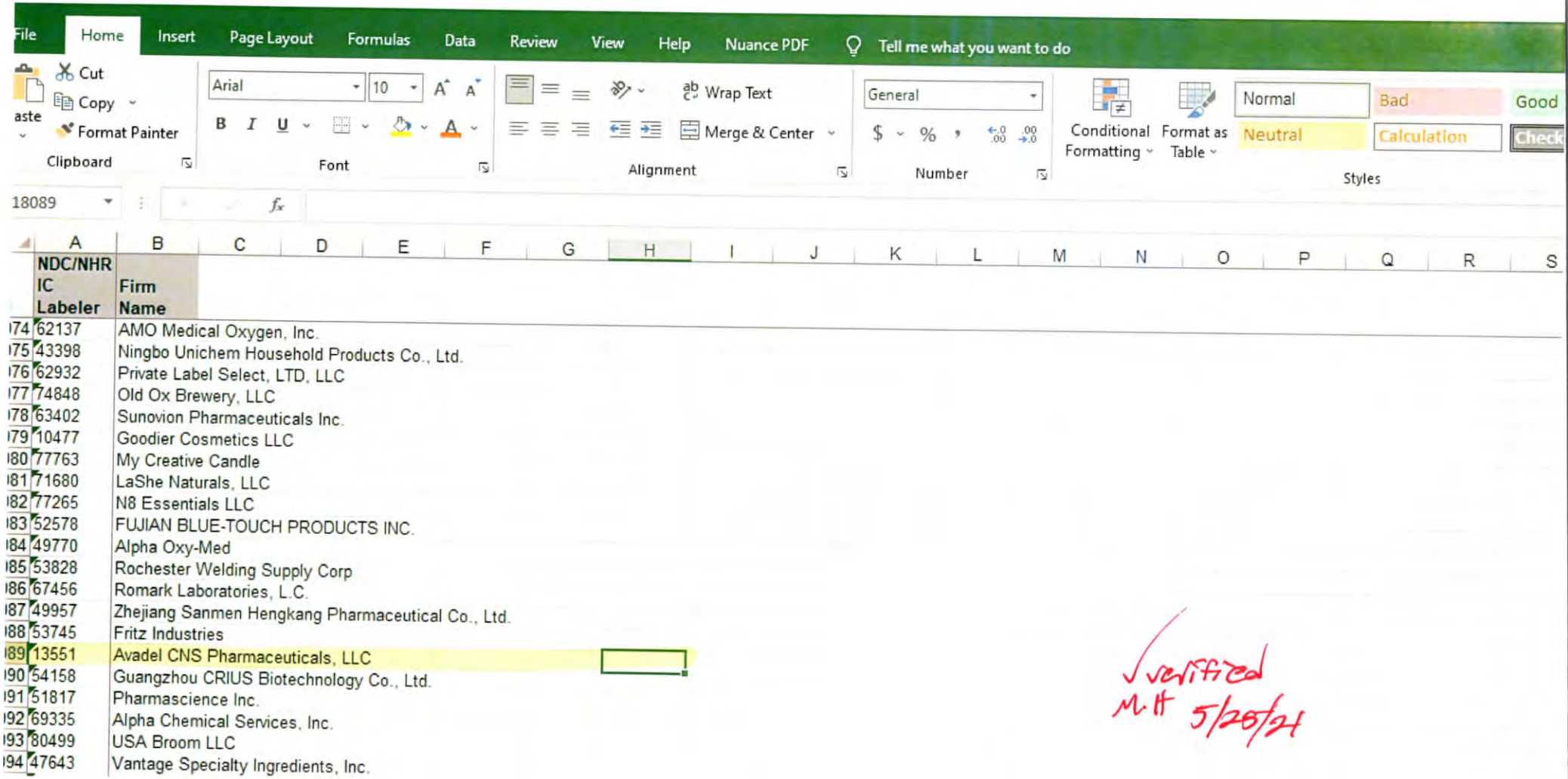
Third Party Logistics Information

For distribution into the commercial supply channels, Eversana Life Sciences, LLC acts as Avadel's Third Party Logistics (3PL) provider to manage the storage and distribution of Avadel's product to Specialty Pharmacies and Distributors throughout the United States. Eversana Life Sciences, LLC's address is:

Eversana Life Sciences, LLC
4580 Mendenhall Rd.
Memphis, TN 38141
(901) 795-7117

Labeler Code:
13551

Avadel's hours of operation are 8:00 am – 5:00pm CST, Monday through Friday



File Home Insert Page Layout Formulas Data Review View Help Nuance PDF Tell me what you want to do

Cut Copy Format Painter — Clipboard

Arial 10 — Font

Wrap Text Merge & Center — Alignment

General — Number

Conditional Formatting Format as Table

Normal Bad Good Neutral Calculation Check — Styles

18089

	A	B
	NDC/NHRIC Labeler	Firm Name
174	62137	AMO Medical Oxygen, Inc.
175	43398	Ningbo Unichem Household Products Co., Ltd.
176	62932	Private Label Select, LTD, LLC
177	74848	Old Ox Brewery, LLC
178	63402	Sunovion Pharmaceuticals Inc.
179	10477	Goodier Cosmetics LLC
180	77763	My Creative Candle
181	71680	LaShe Naturals, LLC
182	77265	N8 Essentials LLC
183	52578	FUJIAN BLUE-TOUCH PRODUCTS INC.
184	49770	Alpha Oxy-Med
185	53828	Rochester Welding Supply Corp
186	67456	Romark Laboratories, L.C.
187	49957	Zhejiang Sanmen Hengkang Pharmaceutical Co., Ltd.
188	53745	Fritz Industries
189	13551	Avadel CNS Pharmaceuticals, LLC
190	54158	Guangzhou CRIUS Biotechnology Co., Ltd.
191	51817	Pharmascience Inc.
192	69335	Alpha Chemical Services, Inc.
193	80499	USA Broom LLC
194	47643	Vantage Specialty Ingredients, Inc.

√ verified
M.H 5/26/21

Heather R. Kruchowski, BS, MBA

[redacted]

An insightful and results driven leader accomplished at Project Management through initiating and implementing changes, building teams and developing processes and systems to benefit the company and shareholders while ensuring global compliance. Strong relationship builder who thinks strategically, communicates effectively, and works collaboratively across the organization to influence decisions. Works as a change agent to bring cohesive execution of company vision while providing the most productive and efficient processes without sacrificing quality or compliance.

- Led a global team inclusive of internal and third-party contributors to harmonize the corporate quality management system across all global sites to ensure compliance with both EU and US GMP standards.
- Implemented full suite of SAAS-based quality system implementation inclusive of all key systems across a global organization in four months.
- First Quality employee for a start-up pharmaceutical company with no commercialized products and grew that organization to include a full staff supporting multiple commercialized products, internal development work and external acquisition and due diligence.
- Experience working with vast variety of product lines inclusive of API manufacturing, solid and liquid oral dose drugs, ointments, parenteral injections, Class II medical device, and combination drug/device nasal spray.
- Full confidence and experience working with US FDA and other regulatory parties through inspection management and execution, response development and remediation follow-through. Experienced with significant compliance remediation for organizations with no systems to those with poor systems including work post 483 and Consent Decree.
- Excellent team management skills for direct reports and outside partners and contributors within a global setting bridging many time zone and cultural differences. Proven record in development of key contributors through mentoring and leadership through demonstration.

PROFESSIONAL EXPERIENCE

Senior Director, Quality US Operations – *May 2018 – Present*

Director, Quality Operations – *Mar 2013 – May 2018*

Avadel Pharmaceuticals (formerly Eclat Pharmaceuticals)

- Head of Quality responsible for the direction of all quality activities associated with US Operations; including establishing, implementing and maintaining systems and / or services to assure product quality and full compliance to cGMP and other regulatory requirements.
- Provide leadership in sustaining GMP compliance within all departments integrating risk- and scientific-based Quality Management Systems.
- Evaluate all systems, procedures, and metrics to drive consistency and promote best practices and integration within the organization and global partners.
- Host all third-party and regulatory audits, develop audit responses, and support timely completion of remediation or commitments.
- Directs the quality oversight of contract manufacturing/packaging facilities and service providers inclusive of decision making affecting routine production, validation, and product development.
- Ensures the system in place for non-conformances, deviations, customer complaints and other quality related issues is compliant, issues investigated in a timely manner and corrective/preventive actions are assigned and completed as required.
- Ensure that all issues (such as Field Alerts, Recalls, or other market actions) are reported to the agency as required within predefined time limits.
- Directs and manages all aspects of Quality Systems, Quality Operations, Validation, and Vendor Management.

Consent Decree Integrator & New Product Planning –*Aug 2011 – Mar 2013*
Nesher Pharmaceuticals (formerly KV Pharmaceuticals)

- Ensured all Consent Decree obligations and commitments are met according to specified deliverable timelines.
- Provided leadership in sustaining CD compliance within all departments integrating all CD and Quality Management Systems. Under my lead, we were successfully able to reduce the required amount of third party GMP oversight and auditing by 75% resulting in budgetary savings in excess of 10 million dollars.
- Led task teams for process simplification to strengthen compliance and increase efficiency.
- Fostered vertical and horizontal integration of systems, initiatives, and changes within the Nesher Organization.
- Developed and implemented plans for new products introduction.
- Assisted in evaluating systems, procedures to drive consistency and promote best practices and integration within the organization.
- Provided support during third-party/regulatory audits, assist in the development of audit responses, and support timely completion of third-party audit commitments.
- Direct Quality Oversight in the development of new and the reintroduction of pre-Consent Decree products.

Quality Assurance Manager – *Aug 2010 – Aug 2011*

- Responsible for the quality oversight of multiple manufacturing/packaging facilities including direct management of a multi-tiered organization supporting 24-hour operations involving 150 personnel.
- Oversight of and responsibility for Quality issues, decisions affecting routine production, and the coordination of cGMP training within the plant.
- Ensured Non-conformances, Deviations, Customer Complaints, and other quality related issues were investigated in a timely manner and corrective/preventative actions are assigned and completed as required.
- Ensured all batches released to market or for further processing complied with all internal and external requirements.

TrackWise Coordinator - *Dec 2008 – Jul 2009, Apr 2010 – Aug 2010*

- Managed projects in the TrackWise electronic process management system. Project types include Change Control, Nonconformance, Planned Deviation, Investigations and CAPA.
- Ensured timely completion of investigations and corrective actions.
- Performed final review of investigations and corrective actions to assess for complete identification of root cause and effective implementation of corrective actions.
- Developed and reported systemic metrics to executive management.
- Developed a Quality System Dashboard reporting quality system status as compared to defined cycle time targets.

Quality Assurance Supervisor – *Apr 2007 - Dec 2008, Jul 2009 – Apr 2010*

- Managed a group of four direct reports responsible for performing floor level quality assurance checks of compression start ups, packaging line start ups, in-process AQL analysis, Annual Product Inspections.
- Primary quality contact for the off-shift operations.
- Served as the quality representative for the SWAT team to improve line clearance practices during product changeover of packaging lines.
- Chaired the corporate objective project for FY07 to reduce the number of repeat NCRs.
- Served as the primary FDA inspection coordinator.

Senior Quality Assurance Specialist *Jun 2004 - Apr 2007*
Sigma-Aldrich Corporation (Currently Millipore-Sigma)

- Served as the primary FDA contact during on-site inspection.
- Designed and implemented a Management of Change program supporting ISO, cGMP, and PSM business units.
- Designed and implemented a CAPA program supporting ISO and cGMP business units.
- Served as the project manager in the implementation of a Business Process Management System. Led a cross-functional team consisting of operations, quality control, process development and quality assurance.
- Developed and implemented a departmental training program to ensure that all employees training requirements are documented and any deficiencies identified and addressed.

Quality Assurance Specialist – *Mar 2001 - Jun 2004*

- Hosted all customer audits including the management of the inspection process through the receipt, response and closure of any observations.
- Developed and conducted general cGMP training for all personnel directly and indirectly involved with cGMP operations. Presented training material in multiple formats from one-on-one, small groups, and large conference centers.
- Reviewed and releasee raw materials and components for use in cGMP processes.
- Wrote and reviewed technical documents describing company policy and department procedure.
- Reviewed and approved Certificates of Analysis for cGMP material prior to the release and distribution of product to the customer.
- Answered general quality questionnaires and animal origin and risk questionnaires.
- Led and participated in many process improvement exercises to increase the efficiency and productivity of the company, to ensure the safety and quality of the product, and to control systems and coordinate their activities to ensure a uniform, seamless interaction.

Chemist I – *Jan 1999 - Mar 2001*

- Analyzed samples for purity, functionality, and accuracy in the cGMP Tissue Culture and Microbiology quality control lab.
- Coordinated the evaluation of raw sera for use in cGMP manufacturing including: specification review, assignment of tests, review of results and vendor documents, and release of material for general plant use.
- Coordinated all testing performed by outside contract laboratories.
- Reviewed the work of coworkers to ensure proper cGMP compliance and product processes and specifications.
- Served as chairperson for facility Safety committee.

▪ EDUCATION

- **Master of Business Administration** – Lindenwood University, St. Charles, Missouri
- **Bachelors of Science, Biology** – Southern Illinois University, Edwardsville, Illinois

Avadel Pharmaceuticals

Product List

Sodium Oxybate for Extended-Release Oral Suspension

NDC	Dosage
13551-001-07	4.5g - 7ct
13551-001-30	4.5g - 30ct
13551-002-07	6.0g - 7ct
13551-002-30	6.0g - 30ct
13551-003-07	7.5g - 7ct
13551-003-30	7.5g - 30ct
13551-004-07	9.0g - 7ct
13551-004-30	9.0g - 30ct

STATE OF MISSOURI
BOARD OF PHARMACY

OBSERVATION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY OR DRUG DISTRIBUTOR	LICENSE NUMBER	CLASS	INSPECTION DATE
Avadel CNS Pharmaceuticals LLC 16640 Chesterfield Grove Road Ste. 200 Chesterfield MO 63005	2021000490	DD	1/6/2021

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Heather Kruchowski	

PHONE	Fax	Email
6364491839	6364491850	hkruchowski@avadel.com

INSPECTION TYPE: **Initial**

Inspector: Dan Vandersand

Acknowledged By: Heather Kruchowski

Observations:

-Initial inspection satisfactory

Comments:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBIP7624

Application/License No. _____

AVADEL CNS PHARMACEUTICALS LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 16640 Chesterfield Grove Road, Suite 200 Chesterfield, MO 63005 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 24, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of March, 2021.

APPLICANT/PRINCIPAL
AVADEL CNS PHARMACEUTICALS LLC

COMPANY

Authorized Representative

SURETY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Eiston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of

Witness

Witness

SIGNED and SEALED in the presence of.

Witness Paul M. Allen

Witness Rachel Fore

Countersigned by

Nevada Resident Agent N/A

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-12
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: AON RISK SERVICES CENTRAL INC
Agency Code: 83-553702

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, *up to the amount of* Unlimited :

Derek J. Elston, Ann Mullins, Christopher P. Troha, Marcia K. Cesafsky, Jennifer L. Jakaitis, Bartlomiej Siepierski, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 6, 2015 the Companies have caused these presents to be signed by its Senior Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

John Gray, Assistant Secretary

M. Ross Fisher, Senior Vice President

STATE OF CONNECTICUT }
COUNTY OF HARTFORD } ss. Hartford

On this 5th day of January, 2018, before me personally came M. Ross Fisher, to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is the Senior Vice President of the Companies, the corporations described in and which executed the above instrument; that he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that he signed his name thereto by like authority.

Kathleen T Maynard
Notary Public
My Commission Expires July 31, 2021

CERTIFICATE

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of March 24th, 2021

Signed and sealed at the City of Hartford.

Kevin Heckman, Assistant Vice President

ACKNOWLEDGEMENT BY SURETY

STATE OF ILLINOIS
COUNTY OF COOK

On this 24th day of March, 2021, before me, Bartlomiej Siepierski, a Notary Public, within and for said County and State, personally appeared Derek J. Elston to me personally known to be the Attorney-in-Fact of and for Hartford Fire Insurance Company and acknowledged that s/he executed the said instrument as the free act and deed of said Company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

Notary Public in the State of Illinois
County of Cook

OFFICIAL SEAL
BARTLOMIEJ SIEPIERSKI
NOTARY PUBLIC, STATE OF ILLINOIS
COOK COUNTY
MY COMMISSION EXPIRES 09/16/2023

TwoLabs PHARMA SERVICES

Avadel Pharmaceuticals

RECEIVED
MAY 21 2021
NEVADA STATE BOARD OF PHARMACY

05/17/2021

Via Fed Ex

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

To Whom It May Concern:

On behalf of Avadel CNS Pharmaceuticals, LLC, attached is Avadel CNS Pharmaceuticals, LLC's application for Wholesale Distributor.

Avadel CNS Pharmaceuticals, LLC ("Avadel CNS") is a virtual manufacturer located in Chesterfield, MO. Please see the enclosed license and inspection report from the State of Missouri.

Avadel CNS's products will be manufactured by a contract manufacturer and will be stored and distributed by Avadel CNS's third-party logistics provider, Eversana Life Sciences, who is licensed to ship pharmaceutical products in your state. ***Please note as a virtual manufacturer, product will not be manufactured, stored, or distributed from Avadel CNS's facility.***

Avadel CNS's products are controlled substances. As a virtual manufacturer, Avadel CNS cannot obtain a DEA license. Avadel CNS's third-party logistics provider holds the registration with the DEA. Enclosed is a copy of Eversana Life Sciences DEA license.

I hope this information is helpful as you review Avadel CNS's application. If you have any questions regarding this application, please contact me at 614-371-5773 or via email at JerriLynn.Ford@twolabs.com. Please also address all written communication to me. My address is 200 Marie Ave., Pickerington, OH 43147.

Thank you in advance for your consideration.

Jerri Lynn Ford
Licensing Analyst
Two Labs Pharma Services

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Corium, Inc.

Physical Address: 4558 50th Street SE

City: Grand Rapids State: MI Zip Code: 49512

Telephone Number: (616) 646-4563 Fax Number: _____

Toll Free Number: _____

E-mail: duaneg@coriumintl.com Website: www.coriumintl.com

Facility Manager: Duane Gibson

Professional qualifications and experience of facility manager: _____
See attached resume

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☒ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Duane Gibson

Original Signature of Person Authorized to Submit Application, no copies or stamps

Duane Gibson

Print Name of Authorized Person

04-16-21

Date

Board Use Only Date Processed:_____ Amount: 500 Check # 3543415

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: DE

Parent Company if any: Corium, Inc.

Mailing Address: 4558 50th Street SE

City: Grand Rapids State: MI Zip: 49512

Telephone: (616) 646-4563 Fax: N/A

Contact Person: Duane Gibson

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Gurnet Holding Company (Name) 55 Cambridge Parkway, Suite 401, Cambridge, MA 02142 (Business Address)

b) Waypoint GPC Limited (Name) Ensign House, 29 Seaton Place, St Helier, Jersey, United Kingdom, Je1 1ZZ (Business Address)

c) _____ (Name) _____ (Business Address)

d) _____ (Name) _____ (Business Address)

2) Provide the number of shares issued by the corporation. 31,578,042

3) What was the price paid per share? $12.50

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

19TMP-185772

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

VOID

CORIUM, INC.
4558 50TH ST SE
GRAND RAPIDS, MI 49512

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

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

YOUR LICENSE MUST BE DISPLAYED IN A PROMINENT PLACE.

GRETCHEN WHITMER
GOVERNOR

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

CORIUM, INC.
4558 50TH ST SE
GRAND RAPIDS, MI 49512

LICENSE NO.
5306001980

EXPIRATION DATE
8/29/2021

19206110738

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

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CORIUM, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF MAY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3496754 8300

SR# 20211635344

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203146381

Date: 05-06-21

Corium

Ownership Information

Corium, Inc. is a privately held company held by stockholders. It is held 76% by Waypoint GPC Limited and 24% by Gurnet Holding Company c/o Waypoint International GP LLC.

Company Information

Company Name: Corium, Inc.
Address: 4558 50th Street SE
City, State, Zip: Grand Rapids, MI 49512
Phone: (616) 646-4563 / Website: http://www.coriumintl.com/ / E-mail: Duaneg@coriumintl.com
FEIN: 38-3230774 / State of Formation: DE / Date Incorporated: 02/28/2002

Officers

Perry Sternberg, Chief Executive Officer
4558 50th Street SE
Grand Rapids, MI 94025
psternberg@coriumintl.com
SSN: [redacted]
DOB: [redacted]
DL: [redacted]

John Miller, Chief Financial Officer
4558 50th Street SE
Grand Rapids, MI 94025
jmiller@coriumintl.com
SSN: [redacted]
DOB: [redacted]
DL: [redacted]

Steven Gersten, Chief Legal and Compliance Officer
4558 50th Street SE
Grand Rapids, MI 94025
sgersten@coriumintl.com
SSN: [redacted]
DOB: [redacted]
DL: [redacted]

Duane Gibson, Director of Quality Assurance
4558 50th Street SE
Grand Rapids, MI 94025
duaneg@coriumintl.com
SSN: [redacted]
DOB: [redacted]
DL: [redacted]



Home Search + New Help

Register for an Account Login

NOTE: If you would like to Renew your license follow these instructions:

- You must use a desktop or laptop computer to complete the registration and renewal process.
- Login to MiPLUS.
- Click on the "Licenses" tab.
- Find your License Number under the "Record Number" column. Click on the "Renew License" link located under the "Action" column.

Home Licenses Enforcement

Advanced Search

Licensed Professional Information: Manufacturer 5306001980

Licensee Detail

License Type:
Manufacturer

License Number:
5306001980

Organization Name:
CORIUM, INC.

DBA Trade Name:

License Issue Date:

08/29/2002

License Expiration Date:

08/29/2021

License Status:

Active

County:

Kent

CONTROLLED SUBSTANCE LIST

City: Grand Rapids

State or Province: Michigan

ZIP or Postal Code: 49512

CS Record Number: 5315011977

CS Status: Active

CS Expiration Date: 08/29/2021

▸ <--- Click to view Public Documents

© 2016 State of Michigan.

Drug Establishments Current Registration Site

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

New Search

Search Results for **Corium**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Corium, Inc.	3003693105	098238541	MANUFACTURE;	4558 50th Street SE, Grand Rapids, Michigan (MI) 49512, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries

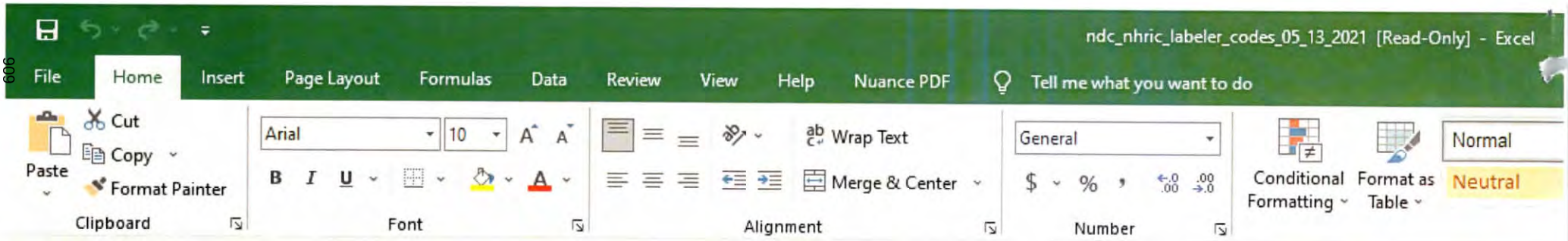
Previous 1 Next

Data Current through: Thursday, May 13, 2021

Return to Drug Firm Annual Registration Status Home Page

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

verified M.H 5/13/21



E8843

	A	B
1	NDC/NHRIC Labeler	Firm Name
8828	77279	Seber Design Group, LLC
8829	80097	Antica Farmacista, LLC
8830	79194	Brave Runner LLC
8831	68752	TriMarc Labs
8832	55695	Department of State Health Services, Pharmacy Branch
8833	18860	Jazz Pharmaceuticals, Inc.
8834	61649	Bio Spectra
8835	64682	Galderma Laboratories, L.P.
8836	81428	SINGULAR ENTERPRISES LLC
8837	79773	Texas State University
8838	74632	Sagamore Whiskey, LLC
8839	23664	Bjorn Pharmaceuticals LLC
8840	72495	Millicent U.S., Inc.
8841	64321	Continental Research Corporation
8842	63299	FEI FAH MEDICAL MANUFACTURING PTE LTD
8843	65038	Corium, Inc.
8844	57994	Mylan Laboratories Limited
8845	49725	HandsFree
8846	81101	CERGOMEX IMPORTS LLC
8847	52909	KEN LIFESCIENCE
8848	79858	Cummings Investment Bankers, Inc.
8849	70554	The Feel Good Lab LLC
8850	74833	U.S. Oil Chem, LLC.
8851	63148	APOLLO HEALTH AND BEAUTY CARE

✓ Verified MH 5/14/21

Corium

Description of Operations

Corium, Inc. is a Self- Manufacturer. Corium, Inc. is a private company with stock holders and is in Grand Rapids, MI. Corium, Inc.'s products will be distributed to customers by their Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are a self-manufacturer and products are manufactured at:

Corium, Inc.
4558 50th Street SE
Grand Rapids, MI
49512
Contact Person:
Duane Gibson
Contact Number:
(616)646-4563
FDA Establishment No:
3003693105

Corium, Inc.'s hours of operation are 24 hours per day.

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

±

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **corium**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Corium, Inc.	3003693105	098238541	MANUFACTURE;	4558 50th Street SE, Grand Rapids, Michigan (MI) 49512, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Thursday, May 6, 2021

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Corium

Ownership Information

Corium, Inc. is a privately held company held by stockholders. It is held 76% by Waypoint GPC Limited and 24% by Gurnet Holding Company c/o Waypoint International GP LLC.

Company Information

Company Name: Corium, Inc.
Address: 4558 50th Street SE
City, State, Zip: Grand Rapids, MI 49512
Phone: (616) 646-4563 / Website: http://www.coriumintl.com/ / E-mail: Duaneg@coriumintl.com
FEIN: 38-3230774 / State of Formation: DE / Date Incorporated: 02/28/2002

Officers

Perry Sternberg, Chief Executive Officer

John Miller, Chief Financial Officer

Steven Gersten, Chief Legal and Compliance Officer

Duane Gibson, Director of Quality Assurance

Contact

www.linkedin.com/in/duane-gibson-92431243 (LinkedIn)

Top Skills

FDA

GMP

Quality System

Duane Gibson

Director, QA and Regulatory at Corium International

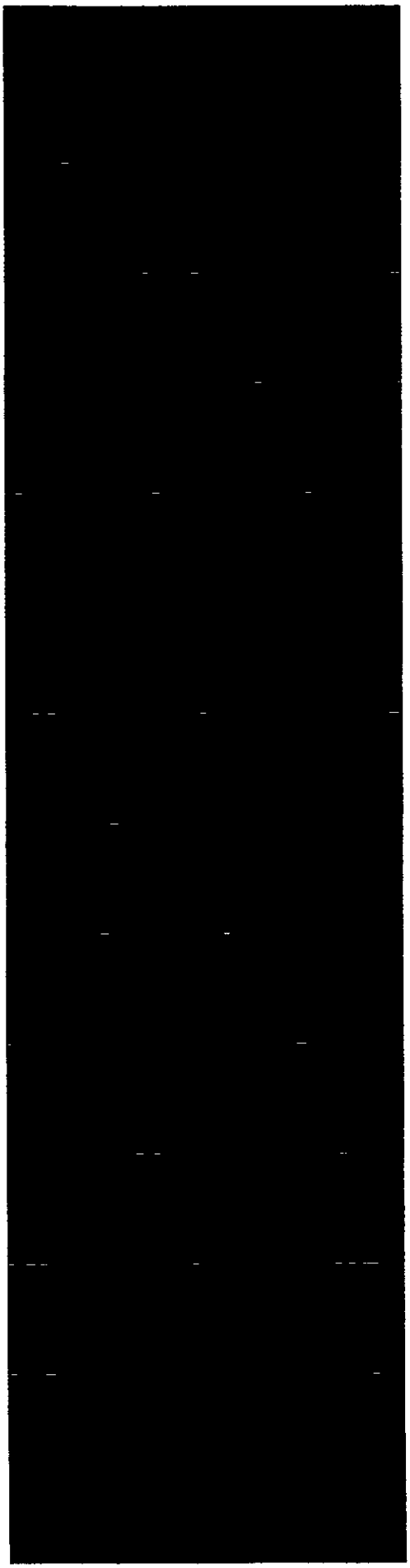
Summary

A highly motivated, goal oriented professional with 20+ years of progressive experience in the pharmaceutical, medical device, and consumer product industry. Well rounded background in developing quality assurance, quality control, and regulatory systems with an emphasis on regulatory compliance, customer focus, and bottom line performance. Well organized, self starter with proven ability to work independently and as a team collaborator. Manage multiple projects and work effectively with multiple departments and customers to meet deadlines and accomplish objectives

Experience

Corium International
Director, QA and Regulatory
2001 - Present (19 years)

•Responsible for all aspects of the Quality Assurance, Quality Control, and Regulatory compliance for the development and manufacture of pharmaceutical, OTC drug, medical device, and cosmetic products in both clinical and commercial manufacturing environments.
•Interpret multiple regulations and interact with various regulatory bodies including the FDA, DEA, and ISO to establish quality compliance strategies to ensure GMP and regulatory compliance.
•Lead and manage FDA, DEA, ISO, customer, and internal audits.
•Manage FDA Pre-Approval Inspections for new product approvals.
•Complete FDA and DEA regulatory reports
•Direct work on multiple New Drug Application (NDA) products, Abbreviated New Drug Application (ANDA) products, and cosmetic products.
•Established and manage customer complaint, deviation, and CAPA investigation and reporting systems.
•Author and implement quality agreements with customers and suppliers. Establish working relationships with contract customers to ensure their expectations are met.



•Responsible for department budget and planning activities for current and future personnel and equipment.

Amway
QA Scientist
1991 - 2001 (10 years)

Education

Ferris State University
Bachelor of Applied Science (B.A.Sc.) · (1985 - 1990)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0798237

Application/License No. _____

Corium, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
4558 50th Street SE, Grand Rapids, MI 49512, as
(Address of Applicant/Principal)
PRINCIPAL, and Harco National Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Illinois
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Newark Center, 20th Floor, Newark, NJ 07102 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 2/24/2021.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Bond No. 0798237

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregete liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principel and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of February, 20 21.

APPLICANT/PRINCIPAL

COMPANY
Corium, Inc.

Authorized Representative
John Miller, CFO

SURETY
Harco National Insurance Company

Surety Company's Representative

Valerie Garcia, Attorney-in-fact
print name

ANA WILSON
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires Oct. 14, 2022

SIGNED and SEALED in the presence of:

Witness **Ivan Tosques**

Witness **Erin Tierney**

SIGNED and SEALED in the presence of:

Witness **Joseph Takeuchi**

Witness **Lana Zeidan**

Countersigned by:

not applicable
Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0798237

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

VALERIE GARCIA, CHRISTINA BURTON, ALICIA DASS, PETER TAM, KELLY HOLTEMANN, THOMAS E. HUGHES, CHARLES R. SHOEMAKER, MARK M. MUNEKAWA, NERISSA S. BARTOLOME, JOAN DELUCA, SARA RIDGE, PATRICK R. DIEBEL, YVONNE RONCAGLIOLO

San Francisco, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2019

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1984 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2019, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC No. 50078910 NEW JERSEY My Comm. Exp. 04-04-2023

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, February 24, 2021

A00467

Irene Martins, Assistant Secretary

TwoLabs PHARMA SERVICES

Corium

May 6, 2021



Via Fed Ex

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

To Whom It May Concern:

On behalf of Corium, Inc. attached is Corium, Inc.'s application.

Corium's products are manufactured at their facility and they also use a separate contract manufacturer. All products are distributed by a Third-Party Provider, who meets licensure requirements to ship pharmaceutical products into your state. Corium, Inc.'s product has a controlled substance component. Accordingly, Corium has a DEA registration.

I hope this narrative is helpful as you review Corium, Inc.'s application. If you have a question regarding this application, please contact me at 614-620-6898 or via email at krista.jones@twolabs.com. Please also address all written communication to me. My address is 210 Victorian Dr. Commercial Point, OH 43116.

Thank you in advance for your consideration.

Krista Jones
Sr. Licensing Analyst
PharmaLicense

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Covis Pharma US, Inc.

Physical Address: 1150 1st Avenue, Suite 910

City: King of Prussia State: PA Zip Code: 19406

Telephone Number: 484-322-2349 Fax Number: N/A

Toll Free Number: N/A

E-mail: atenuto@covispharma.com Website: https://www.covispharma.com/

Facility Manager: Alfred F. Tenuto Jr.

Professional qualifications and experience of facility manager: See Attachment B

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☑ Practitioners ☑ Hospitals ☑ Wholesalers
☑ Other: Distributors, Nursing Home Pharmacies, Clinics

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

Rec. 6/11/21

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration) See Attachment C

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☑ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment D
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Alfred F. Tenuto Jr.
Print Name of Authorized Person

5-17-21
Date

Board Use Only	Date Processed:_____	Amount: $500 Check # 00000843178

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Covis Holdings US, Inc.

Mailing Address: 1150 1st Avenue, Suite 910

City: King of Prussia State: PA Zip: 19406

Telephone: 484-322-2349 Fax: N/A

Contact Person: Alfred F. Tenuto Jr.

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Covis Holdings US, Inc. — 1209 Orange Street, Wilmington, DE 19801
Name — Business Address

b) _____
Name — Business Address

c) _____
Name — Business Address

d) _____
Name — Business Address

2) Provide the number of shares issued by the corporation. 1,000

3) What was the price paid per share? $0.01

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment E

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment F

Attachment A

Regarding the Resident State License and Verification

As a virtual manufacturer (i.e. a company that does not physically manufacture, handle, or distribute its own products), the resident state licensing agency, the Pennsylvania Department of Public Health (Department), has determined that the company is not required to hold a license. When received, confirmation from the Department will be provided.

Attachment F

Delaware Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COVIS PHARMA US, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MAY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7885369 8300

SR# 20211729246

Authentication: 203183984

Date: 05-12-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment B

Facility Manager's Resume

Contact

www.linkedin.com/in/al-tenuto-bba39011

Top Skills

Cross-functional Team Leadership
Managed Care
Urology

Al Tenuto

President Covis USA

Summary

Pharmaceutical Executive
Experienced in: Creating US Commercial footprint. Manage all aspects of US P&L for portfolio exceeding $400 million in net sales.

Cross functional leadership: Sales/Marketing, Medical with comprehensive payer, channel and federal/state government strategy: Managed markets:Government payer expertise: Wholesale / retail product/ specialty distribution/pharmacy: Pricing-WAC changes/ contract pricing: Government price reporting: Payer marketing: Reimbursement: HUB services: Copay cards: REMS:Business development integration:Channel Strategy: Government affairs:Health economics: PBM & Managed care expertise: Devise contract strategies: BD diligence and On-boarding.
Process-oriented, quality-driven, customer-focused Executive with significant experience in strategic planning and tactical execution, commercial / government account development and leadership and distribution channel creation / management. Reputation for devising and incorporating processes, procedures, and programs that minimize risk, increase sales, decrease costs, and improve profitability. Skilled at attaining access, negotiating favorable contracts, and achieving positive formulary status for oral, injectable, and biologic products. Strengths lie in inspiring and motivating direct reports and cross-functional team members by championing break-through ideas, removing roadblocks, and garnering buy-in to external customer-focused practices in all business dealings.

Experience

Covis Pharma
7 years 2 months

President Covis USA
November 2020 - Present (4 months)

Executive Vice President, US Commercial Covis USA
June 2019 - November 2020 (1 year 6 months)

Senior Vice President, Market Access
March 2016 - May 2019 (3 years 3 months)

Charged with the task to integrate all strategic and functional channel access, coverage and reimbursement activities of a start-up specialty pharmaceutical company under one centralized focus. Responsibilities include the development, creation, and oversight of channel access strategy, distribution, trade relations, pricing, and payer access including: relationships with all payer segments, oversight of contracting and administration, and compliance with government pricing and reporting. Responsible for supporting valuation through BD efforts by diligencing impact of price, reimbursement and payer access for potential asset purchases or divestitures. Lead TSA and on-boarding process for completed transactions.

Vice President, Market Access
January 2014 - February 2016 (2 years 2 months)

Charged with the task to integrate all strategic and functional channel access, coverage and reimbursement activities of a start-up specialty pharmaceutical company under one centralized focus. Responsibilities include the development, creation, and oversight of channel access strategy, distribution, trade relations, pricing, and payer access including: relationships with all payer segments, oversight of contracting and administration, and compliance with government pricing and reporting.

Branded Access Solutions
Principal
December 2015 - June 2020 (4 years 7 months)

Vivus Inc
Senior Director Market Access
March 2012 - November 2013 (1 year 9 months)

Challenged to devise, build and execute a comprehensive Market Access strategy to support the launch of the first obesity medication in more than 13 years. Lead a group of 4 direct reports and an overall department of 25 FTE's and consultants. Responsible for developing channel needs based on product REMS requirements. Partner with DC lobbying firm to remove Medicare Part D exclusion for obesity medications. Develop phamacoeconomic model, tools/ value proposition for Account teams to increase access for Qsymia. Partner with employer coalitions to "normalize" the treatment of obesity to ultimately change plan benefit design. Report to Chief commercial officer and sit on Vivus executive operations committee to help set course for the commercialization of Qsymia and future commercial opportunities.

Selected accomplishments:

• Partnered with Vivus Medical to create and negotiate with FDA to modify Qsymia REMS program to expand the channel beyond "Mail order" to retail channel as part of product approval. Expansion to retail creates more than a $750 million in additional value per year in the long term forecast for Qsymia.

• Successfully hired, trained and developed internal Market Access team to manage contracting, establish presence at key conferences-(AMCP, PCMA, NACDS) create promotional tools for field team(budget impact model, value proposition, supplements and journal advertising) establish price reporting procedures, compliance reporting and pull through plan for sales force.

• Lead effort in DC to change Medicare Part D exclusion for pharmacological treatment for weight loss. Coordinate with coalition of manufacturers in obesity space, key advocacy groups, consultants and lobbyist. Bill has been introduced, manuscript published and currently in the process of scoring cost of treatment with the CBO.

• Highly functioning NAM team focused on executing payer and employer strategy. Significant wins at Kaiser, ESI/Medco and Aetna.

Eli Lilly

13 years 3 months

Director of Trade Accounts

December 2009 - March 2012 (2 years 4 months)

.Enlisted to develop and incorporate the distribution pricing and fee-for-service models for 23 wholesalers (McKesson, Cardinal, AmerisourceBergen, etc.), and nationwide and regional specialty / retail pharmacies (CVS, Walgreen's, Accredo, Curascript, et. al.) to ensure profitability and consistent patient accessibility to products. Interface with C-level executives, purchasing directors, and category managers. Manage a 5-member team charged with

creating product movement. Partner with brand teams, providing input on appropriate offerings at the channel level.

Selected accomplishments:

• Championed the utilization of Six Sigma processes, development of a strong business case, and sourcing / securing 3PL vendors to transport a flammable testosterone product to distributors in collaboration with manufacturing, which resulted in no impact to fee-for-service agreements and saved $50 million in basis point fees.

• Pioneered strategy to discount Gemzar at distributor level to avert part of 1.5 billion loss of business due to product patent expiration while develop authorized generic, projected to realize $150 million in distinct profitability and protect 50% of market share post patent.

• Avoided pulling $250 million in products from distribution channels and realized zero returns subsequent to theft of $80 million in products from Connecticut warehouse by proving to leadership / customers that existing quality control and chain-of-custody distribution measures kept affected products out of US. Procedures and reporting methods viewed by customers as best-in-class standard for dealing with product theft.

• Realized $1.5 million in distribution and $6 million in tax savings, moved FFS 14 basis points, and estimated distinct profitability of $30 million in 2010 by transitioning Cardinal Health to a single-point distribution system.

Director – Specialty Products

January 2007 - December 2009 (3 years)

Promoted to create and execute the business development, access, contracting, and formulary access strategies for Human Growth Hormone (HGH), Anti-depressant, and Osteoporosis / Oncology injectible products. Created and developed pricing strategy, and short- / long-term vision for the Specialty Products segment. Collaborated with managed care NAMs and RAMs to develop relationships with key decision makers at regional and national accounts, including Aetna, Cigna, Anthem Wellpoint, Highmark, CVS/Caremark, Medco-Accredo, ESI-Curascript, Icore, and UMCP to achieve specialty pharmacy goals. Hired, trained, coached, and developed 6 specialty account managers in geographically disbursed locations in the US. Coordinated cross-functional efforts across Managed Care, Government, and Trade divisions.

Selected accomplishments:

• Realized unprecedented levels of access for Humatrope (78% of covered lives), exceeded $202 million sales goal by 104%, and attained pricing discounts of 17% (versus 19% goal) despite position as 1 of 8 competitive

products in the market place by educating pharmacy directors, incorporating creative contracting strategies, and transitioning drug from medical to pharmacy benefit.

• Achieved sole selection of Humatrope by Highmark's president by formulating an innovative split contact offer between Medmark and Highmark (10% upfront and 20% back-end discount) and winning the total business at 32% rebate versus competitor's offer of 37%.

• Persuaded Zyprexa brand to pull 3% upfront discount to LTC GPOs subsequent to analyzing data and developing a business case detailing risk analysis, which returned $26 million to the bottom-line and resulted in no loss of prescriptions.

• Influenced leadership and payer teams to incorporate a new structure centered around control versus services contracting, which decreased rebates, reduced legal risks, and opened process for future brands to successfully utilize distribution channel.

District Sales Manager – Diabetes Franchise (2004-2006)

February 2004 - December 2006 (2 years 11 months)

Engaged by senior management to turnaround an underperforming district into a top-performing entity. Analyzed current performance, developed action plan, and implemented strategies to increase sales of Humalog, Byetta, Cialis, and Cymbalta with Endocrinologists, Urologists, and Primary Care Physicians. Recruited, hired, trained, and developed 10-14 top sales performers. Provided input to brand teams on pull through initiatives.

Selected accomplishments:

• Catapulted district ranking from #30 to #7 in a two-year timeframe by training sales force on selling skills, account targeting strategies, clinical product knowledge, and large account management tactics. Won the Coaching and Peer Awards in 2006.

• Retained 100% of high-performing sales team members; instrumental in the promotion of 9 direct reports to positions of greater responsibility within the company.

• Spearheaded direction / development of a strong Medicare Modernization Act communication plan for utilization by entire PCP sales force

Senior Account Executive (National Account Manager)

January 1999 - January 2004 (5 years 1 month)

Recruited to facilitate the sales, marketing, pull through, distribution, and inventory management efforts for entire product portfolio at national chain and wholesale accounts, including CVS, AmerisourceBergen, Oncology Supply, KinRay, and Brooks. Orchestrated implementation of brand objectives,

including compliance and persistency, direct-to-consumer advertising, and disease state management program incorporation. Managed fluctuations and continuous availability of products by incorporating comprehensive inventory management systems and overseeing collaborative relationship efforts between sales forces, managed care personnel, and customers.
Selected accomplishments:
• Protected $250 million in private-label insulin business and maintained 50% market share by devising a focused marketing plan surrounding adherence and POS programs, and creating an innovative partnership with CVS that deflected competitive threats.
• Recognized as "Best Account Manager" by HIRC National Retail Drug Chain Executive Panel; received the Account Manager of the Year (2001), Top Gun (2002) and Peer (2003) Awards.
• Developed and implemented Inventory Management Program to maintain consistent product flow and guarantee end-user access.

VIVUS, Inc.
3 years 1 month

Regional Account Manager
January 1998 - January 1999 (1 year 1 month)

Promoted to secure access and attain positive formulary status for urology products with regional managed care and government accounts in the Eastern Region. Implemented contract decisions and pull through plans, and communicated push through efforts and reimbursement issues to field sales team members. Developed and maintained solid relationships with key decision makers at MCOs, DOD / VA, regional chain headquarters, and wholesalers. Garnered product and disease state support from influential state advocacy groups.
Selected accomplishments:
Achieved 85% managed care coverage in the Eastern region, realized favorable coverage decisions within VISN, and collaborated with territory manager on important government accounts.
Spearheaded creation and incorporation of a program to maintain Erectile Dysfunction coverage within the Department of Defense.

Territory Manager
January 1996 - January 1998 (2 years 1 month)

Managed the New York territory, which encompassed formulating and implementing strategic business development plans to increase sales and

achieve formulary status for products at direct accounts. Conducted field sales and regional computer training for personnel.
Selected accomplishments:
Outperformed established goal by 285% and ranked #2 regionally and #3 nationally in 1997.
Achieved formulary status at Brooklyn, Bronx, Manhattan Veterans Hospitals, and captured direct account relationships at NYU, Cornell University, Montefiore and Columbia University.
Designed a national reimbursement program template to achieve standardization across the company.

ALZA Corporation
Regional Sales Manager
January 1996 - January 1999 (3 years 1 month)

Tapped by senior management to formulate and implement plans to increase sales / distribution, achieve and maintain product coverage, and attain positive formulary status with managed care and government payers in the Northeast Region. Formed and maintained relationships, and provided support to more than 1100 urologists. Analyzed reports and effectively maintained wholesaler inventory and pharmacy supply.
Selected accomplishments:
Instrumental in company achieving $212 million in revenues against initial $25 million goal for transurethral medications.
Collaborated with Key Opinion Leaders in the Urology field in the design and implementation of programs for pharmacy chains and advocacy groups designed to create demand with end-users to increase sales and product utilization.

Osbon Pharmacy
Sales Representative
January 1994 - January 1996 (2 years 1 month)

Recruited to turnaround an underperforming territory into a top-performing entity, charged with representing Erectile Dysfunction products to urologists in private practice and hospital environments in the greater New York area. Devised and executed new business development strategies and managed existing accounts.
Selected accomplishments:
Improved ranking from #12 to #2 and established a 90% market share within the territory in a two-year timeframe.

Achieved major conversions; Earned highest number of clinical application in February and March 1995.

Education

University of Miami

Bachelor of Arts (B.A.), Marine Affairs · (1987 - 1991)

University of Miami

of Master of Business Administration; Bachelor in Arts, 27; Marketing; Marine Science · (1987 - 1991)

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through April 14, 2021

You have searched Finished drug products

Search Results: *'70515'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Altoprev	70515-630-30	60 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA021316	Covis Pharma	70515-630	lovastatin	LOVASTATIN	HUMAN PRESCRIPTION DRUG
Altoprev	70515-628-30	20 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA021316	Covis Pharma	70515-628	lovastatin	LOVASTATIN	HUMAN PRESCRIPTION DRUG
Altoprev	70515-629-30	40 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA021316	Covis Pharma	70515-629	lovastatin	LOVASTATIN	HUMAN PRESCRIPTION DRUG
Alvesco	70515-711-01	80 ug/1	AEROSOL, METERED	RESPIRATORY (INHALATION)	NDA021658	Covis Pharma	70515-711	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG
Alvesco	70515-712-01	160 ug/1	AEROSOL, METERED	RESPIRATORY (INHALATION)	NDA021658	Covis Pharma	70515-712	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG

√verified
M.H 6/16/2021

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Alvesco	70515-711-02	80 ug/1	AEROSOL, METERED	RESPIRATORY (INHALATION)	NDA021658	Covis Pharma	70515-711	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG
Alvesco	70515-712-02	160 ug/1	AEROSOL, METERED	RESPIRATORY (INHALATION)	NDA021658	Covis Pharma	70515-712	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG
BETAPACE	70515-105-10	80 mg/1	TABLET	ORAL	NDA019865	Covis Pharma	70515-105	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
BETAPACE	70515-109-10	120 mg/1	TABLET	ORAL	NDA019865	Covis Pharma	70515-109	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
BETAPACE	70515-106-10	160 mg/1	TABLET	ORAL	NDA019865	Covis Pharma	70515-106	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
BETAPACE AF	70515-116-06	160 mg/1	TABLET	ORAL	NDA021151	Covis Pharma	70515-116	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
BETAPACE AF	70515-119-06	120 mg/1	TABLET	ORAL	NDA021151	Covis Pharma	70515-119	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
BETAPACE AF	70515-115-06	80 mg/1	TABLET	ORAL	NDA021151	Covis Pharma	70515-115	sotalol hydrochloride	SOTALOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
LANOXIN	70515-262-10	100 ug/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	NDA009330	Covis Pharma	70515-262	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG
LANOXIN	70515-260-10	250 ug/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	NDA009330	Covis Pharma	70515-260	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG
LANOXIN	70515-261-10	250 ug/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	NDA009330	Covis Pharma	70515-261	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG
LANOXIN	70515-263-10	100 ug/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	NDA009330	Covis Pharma	70515-263	digoxin	DIGOXIN	HUMAN PRESCRIPTION DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Omnaris	70515-701-01	50 ug/1	SPRAY	NASAL	NDA022004	Covis Pharma	70515-701	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG
Prilosec	70515-625-01	2.5 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA022056	Covis Pharma	70515-625	omeprazole magnesium	OMEPRAZOLE MAGNESIUM	HUMAN PRESCRIPTION DRUG
Prilosec	70515-610-01	10 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA022056	Covis Pharma	70515-610	omeprazole magnesium	OMEPRAZOLE MAGNESIUM	HUMAN PRESCRIPTION DRUG
Rilutek	70515-700-60	50 mg/1	TABLET	ORAL	NDA020599	Covis Pharma	70515-700	riluzole	RILUZOLE	HUMAN PRESCRIPTION DRUG
Sular	70515-501-10	17 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA020356	Covis Pharma	70515-501	nisoldipine	NISOLDIPINE	HUMAN PRESCRIPTION DRUG
Sular	70515-500-10	8.5 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA020356	Covis Pharma	70515-500	nisoldipine	NISOLDIPINE	HUMAN PRESCRIPTION DRUG
Sular	70515-503-10	34 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA020356	Covis Pharma	70515-503	nisoldipine	NISOLDIPINE	HUMAN PRESCRIPTION DRUG
Zanaflex	70515-602-15	2 mg/1	CAPSULE	ORAL	NDA021447	Covis Pharma	70515-602	tizanidine hydrochloride	TIZANIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Zanaflex	70515-604-15	4 mg/1	CAPSULE	ORAL	NDA021447	Covis Pharma	70515-604	tizanidine hydrochloride	TIZANIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Zanaflex	70515-606-15	6 mg/1	CAPSULE	ORAL	NDA021447	Covis Pharma	70515-606	tizanidine hydrochloride	TIZANIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Zanaflex	70515-594-15	4 mg/1	TABLET	ORAL	NDA020397	Covis Pharma	70515-594	tizanidine hydrochloride	TIZANIDINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Zetonna	70515-737-60	37 ug/1	AEROSOL, METERED	NASAL	NDA202129	Covis Pharma	70515-737	ciclesonide	CICLESONIDE	HUMAN PRESCRIPTION DRUG

Showing 1 to 29 of 29 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment D

Nature of Business

Covis Pharma US, Inc. (Covis) is a virtual manufacturer of prescription drugs and devices. Covis will utilize contract manufacturers to produce its product and a licensed third party logistics provider to warehouse and distribute. The company will not physically handle product. Provided is the contact information for the third parties.

Third Party Logistics Providers:

Cardinal Health 105, Inc. Specialty Pharmaceutical Services
501 Mason Road, Ste. 200
LaVergne, TN 37086

Integrated Commercialization Solutions, LLC
420 International Blvd, Suite 500, Brooks, KY, USA 40109
FDA Registration #: 3002478693

Contract Manufacturers:

Kindeva Drug Delivery Ltd
Derby Road
Loughborough
Leicestershire
LE11 5SF, UK (GBR)

Takeda GmbH
Robert-Bosch-Strasse 8
D-78224 Singen
Germany

Patheon Manufacturing Services LLC
5900 Martin Luther Jr. Highway
Greenville, NC 27834

SkyePharma Production SAS
Zone industrielle Chesnes Quest
55 Rue Du Montmurier
ST Quentin Fallavier, 38070
France

Actavis Laboratories FL, Inc.
4955 Orange Dr.
Fort Lauderdale, FL 33314

Jubilant HollisterStier General Partnership
16751 Trans-Canada Hwy
Kirkland, QC H9H 4J4
Canada

AstraZeneca AB
Gärtunavägen
SE-151 85 Södertälje
5WEDEN

Sanofi Winthrop Industrie
56, route de Choisy au Bac
60205 Compiegne
France

Patheon Inc.
111 Consumers Drive
Whitby, Ont. Canada L1N 5Z5

Attachment E

Corporate Officer Information

Covis Pharma US, Inc.

Alfred F. Tenuto Jr.
President

Michael Porter
CEO

Ozgur Kilic
CFO

Francesco Tallarico
General Counsel and Secretary

CADENCE BANK

COPY

PHARMACEUTICAL WHOLESALER IRREVOCABLE STANDBY LETTER OF CREDIT

ISSUING BANK: Cadence Bank, N.A.
2800 Post Oak Blvd.
Houston, Texas 77056

Irrevocable Standby Letter of Credit No. 22224521
May 26, 2021

TO: BENEFICIARY	APPLICANT
Nevada State Board of Pharmacy 985 Damonte Ranch Pkwy. Suite 206 Reno, NV 89521 Attn: Executive Secretary	Covis Pharma US, Inc. 1150 First Avenue Suite 940 King of Prussia, PA 19406

GENTLEMEN:

1. At the request and on the instructions of Covis Pharma US, Inc., we Cadence Bank, N.A. hereby establish in favor of the Beneficiary, the Nevada State Board of Pharmacy (Board), this Irrevocable Standby Letter of Credit (Credit) in the principal sum of Twenty-Five Thousand and 00/100 United States Dollars (US$25,000.00).

2. This Credit is and has been established for the sole benefit of the Board pursuant to the terms of NRS 639.515 pertaining to the initial or renewal application filed by the Applicant/Licensee.

3. This Credit is intended by the parties to serve as a security device for the performance by Applicant/Licensee of its obligations under applicable Nevada law regarding Applicant/Licensee's operation as a pharmaceutical wholesaler.

4. Pursuant to NRS 639.515(4), upon the imposition of any fines or costs by the Board against the Applicant/Licensee, the Board shall be entitled to draw upon this Credit by presentation of a duly executed Certificate of Drawing in substantially the same form as Attachment A, attached hereto, at our office located at the address above.

5. The Certificate of Drawing shall be completed and signed by the Executive Secretary for the Board. Presentation by the Board of a completed Certificate of Drawing may be made in person or by registered mail, return receipt requested.

6. Upon presentation of a duly executed Certificate of Drawing as above provided, payment shall be made to the Board, to an account designated by the Board, in immediately available funds, at such time and place as the Board shall specify.

7. Funds may be drawn in one or more drawings not to exceed the principal sum.

8. If demand for payment does not conform to the terms of the Credit, we shall give the Board prompt notice that the demand for payment was not effected in accordance with the terms of this Credit, state the reasons therefore, and await further instructions.

CADENCE
BANK

9. Upon being notified that the demand for payment was not effected in conformity with the Credit, the Board may correct any such non-conforming demand for payment.

10. All drawings under this Credit shall be paid with our funds. Each drawing honored by us hereunder shall reduce, *pro tanto,* the principal sum. By paying to the Board an amount demanded in accordance herewith, we make no representations as to the correctness of the amount demanded.

11. This Credit will be cancelled in whole or in part only upon receipt by use of a Certificate of Cancellation which shall be in the form of Attachment B, attached hereto and shall be completed and signed by the Executive Secretary of the Board.

12. Communications with respect to this Credit shall be in writing and addressed to us at the address above and shall specifically refer to this Credit by the number above.

13. This Credit may not be transferred or assigned, either in whole or in part.

14. This Credit shall be deemed a contract made under the laws of State of Nevada, and any action related to this Credit shall be filed in the State of Nevada and shall be subject to the laws of the of the State of Nevada.

15. This Credit shall be perpetual until it is cancelled as provided herein.

Therefore, Cadence Bank, N.A. has executed and delivered this Irrevocable Standby Letter of Credit to the Board as of the 26 day of May 2021.

Cadence Bank, N.A.

By: Ken Hogan

Ken Hogan
Executive Vice President

CADENCE
BANK

Attachment A

CERTIFICATE OF DRAWING

ISSUING BANK: Cadence Bank, N.A.
2800 Post Oak Blvd.
Houston, Texas 77056

Applicant/Licensee; Covis Pharma US, Inc.
1150 1st Avenue, Suite 910
King of Prussia, PA 19406

Irrevocable Standby Letter of Credit No. 22224521 dated May 26, 2021

To Beneficiary: Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy. Suite 205
Reno, NV 89521
Attn: Executive Secretary

The undersigned, the Executive Secretary for the Nevada State Board of Pharmacy (Board) hereby certifies to the issuer that:

1. A lawful order imposing fines and/or costs against the Applicant/Licensee has been entered that entitles the Board to draw against Irrevocable Standby Letter of Credit No. 22224S21 (Credit).

2. The undersigned is authorized under the terms of the Credit to present this Certificate of Drawing as the sole means of demanding payment on the Credit.

3. The Board is therefore making a drawing under the Credit in the amount of $_____

4. The amount demanded does not exceed the principal sum.

5. Sums received shall be used by the Board in accordance with the terms of the Credit.

6. The amount of drawing requested shall be payable to the Board in lawful, immediately available funds to be received by the Board at the above address no later that 5:00 PM Pacific time on the _____day of_____20_____

THEREFORE, the undersigned has executed and delivered the Certificate of Drawing on this _____day of _____, 20_____.

NEVADA STATE BOARD OF PHARMACY

BY:
Larry L. Pinson, Pharm D.
Executive Secretary

CADENCE
BANK

Attachment B

CERTIFICATE OF CANCELLATION

ISSUING BANK: Cadence Bank, N.A.
2800 Post Oak Blvd.
Houston, Texas 77056

Applicant/Licensee; Covis Pharma US, Inc.
1150 1st Avenue, Suite 910
King of Prussia, PA 19406

Irrevocable Standby Letter of Credit No. 22224521 dated May 26, 2021

To Beneficiary: Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy. Suite 205
Reno, NV 89521
Attn: Executive Secretary

The undersigned, the Executive Secretary for the Nevada State Board of Pharmacy(Board) hereby certifies to the Issuer that:

1. The license for which the Credit was issued has expired, been revoked, been cancelled, orotherwise is no longer in effect, thereby making the cancellation of the Creditappropriate.

2. The Board therefore requests the cancellation of the above-referencedCredit.

THEREFORE, the undersigned has executed and delivered this Certificate of Cancellation on this_____day of_____, 20_____.

NEVADA STATE BOARD OF PHARMACY

By:_____
Larry L. Pinson, Pharm.D.
Executive Secretary

4MM

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☐ No

Section 1: General Information

Facility Name: DARMERICA LLC

Physical Address: 198 WILSHIRE BOULEVARD

City: CASSELBERRY State: FLORIDA Zip: 32707

Mailing Address (if different from physical address): 198 WILSHIRE BOULEVARD

City: CASSELBERRY State: FLORIDA Zip: 32707

Telephone: (321) 219 - 9111 Website: www.darmerica.com

Name of Designated Representative (DR): KYLE HAMZA, CDR 8812160

Licensing Company Email: submission@darmerica.com DR Email: submission@darmerica.com

Entities the Wholesaler will Serve	Products to be Handled or Wholesaled
☒ Pharmacies	☒ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	☐ Controlled Substances
☐ Hospitals	☐ Hypodermic Devices
☒ Wholesalers	☒ Veterinary Legend Pharmaceuticals
☒ Others: R&D Institutes, University R&D labs	☐ Others: Bulk API

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Amoli Organics Private Limited
Address: Block No. 422, ECP Canal Road, Village-Luna, Taluka-Padra City: Vadodara, India State: Gujarat Zip: 391440

Name: ZCL Chemicals Limited
Address: 3102/B GIDC Industrial State City: Ankleshwar, India State: Gujarat Zip: 393002

Name: SMS Pharmaceuticals Limited
Address: Unit-VII, Kandivalasa (V), Poosapatirega (M) City: Vizianagaram District, India State: Andhra Pradesh Zip: 535204

Name: Swati Spentose Private Limited
Address: A-1/2102,2103, Phase III City: GIDC-Vapi, India State: Gujarat Zip: 396195

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation

State of Incorporation: FLORIDA
Parent Company (if any): DARMERICA, INC (100%)
Corporation Name: DARMERICA LLC
Mailing Address: 198 WILSHIRE BOULEVARD
City: CASSELBERRY State: FLORIDA Zip: 32707
Telephone: (321) 219 - 9111 Email: submission@darmerica.com
Contact Person Name: KYLE HAMZA

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K**	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

KYLE HAMZA

Print Name of Authorized Person Submitting Application

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

05/17/2021

Date

Board Use Only	Date Received: 5/26/2021 ✓ Received	Amount: 500 (CC)

647

Ron DeSantis, Governor

Julie I. Brown, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Wholesale Distributor HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

DARMERICA, LLC

198 WILSHIRE BOULEVARD
CASSELBERRY FL 32707

LICENSE NUMBER: 2220268

EXPIRATION DATE: MAY 31, 2023

Always verify licenses online at MyFloridaLicense.com

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

State of Florida
Department of State

I certify from the records of this office that DARMERICA, LLC is a limited liability company organized under the laws of the State of Florida, filed on April 8, 2016.

The document number of this limited liability company is L16000070478.

I further certify that said limited liability company has paid all fees due this office through December 31, 2021, that its most recent annual report was filed on January 21, 2021, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-sixth day of May, 2021

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

Secretary of State

Tracking Number: 4512541740CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

2021 FLORIDA LIMITED LIABILITY COMPANY ANNUAL REPORT

DOCUMENT# L16000070478

Entity Name: DARMERICA, LLC

Current Principal Place of Business:

198 WILSHIRE BLVD
CASSELBERRY, FL 32707

Current Mailing Address:

198 WILSHIRE BLVD
CASSELBERRY, FL 32707 US

FEI Number: 30-0933895

FILED
Jan 21, 2021
Secretary of State
9455117814CC

Certificate of Status Desired: No

Name and Address of Current Registered Agent:

HAMZA, KYLE
198 WILSHIRE BLVD
CASSELBERRY, FL 32707 US

The above named entity submits this statement for the purpose of changing its registered office or registered agent, or both, in the State of Florida.

SIGNATURE: KYLE HAMZA 01/21/2021

Electronic Signature of Registered Agent — Date

Authorized Person(s) Detail :

Title	AMBR	Title	AMBR
Name	MACINNIS, WAYNE	Name	DARMERICA, INC.
Address	800-425 UNIVERISTY AVE	Address	800-425 UNIVERSITY AVE
City-State-Zip:	TORONTO, ONTARIO M5G 1T6	City-State-Zip:	TORONTO, ONTARIO CANADA M5G 1T6

I hereby certify that the information indicated on this report or supplemental report is true and accurate and that my electronic signature shall have the same legal effect as if made under oath; that I am a managing member or manager of the limited liability company or the receiver or trustee empowered to execute this report as required by Chapter 605, Florida Statutes; and that my name appears above, or on an attachment with all other like empowered.

SIGNATURE: WAYNE MACINNIS OFFICER AND DIRECTOR 01/21/2021

Electronic Signature of Signing Authorized Person(s) Detail — Date

Darmerica LLC.
198 Wilshire Blvd.
Casselberry, FL 32707
Tel: 321-219-9111
Fax: 321-219-9130
www.darmerica.com

DARMERICA LLC:
List of Officers and Directors

Name Kyle (Khaled) Hamza BSc, CDR
Title: Director of Operations and Quality
Business Phone Number: (321) 219-9111

Name Donald Wayne MacInnis
Title: Officer
Business Phone Number: (647) 667 - 3773

Darmerica LLC.
198 Wilshire Blvd.
Casselberry, FL 32707
Tel: 321-219-9111
Fax: 321-219-9130
www.darmerica.com

DARMERICA LLC:
OWNERSHIP STRUCTURE

Owner Information:
Entity Name: Damerica Inc
Shareholder Percentage: 100%
Name and Title: Wayne MacInnis – President/Secretary
Business Address: 425 University Avenue, Unit 800, Toronto, Ontario M5G 1T6, Canada
Business Phone Number: (647) 667-3773
Email: submission@darmerica.com

Drug Establishments Current Registration Site

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

New Search

Search Results for **Darmerica**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
DARMERICA, LLC	3012389174	080233052	RELABEL; REPACK;	198 Wilshire Blvd, Casselberry, Florida (FL) 32707, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries

Previous 1 Next

Data Current through Wednesday, May 26, 2021

Return to Drug Firm Annual Registration Status Home Page

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Verified M.H 5/26/2021

Drug Establishments Current Registration Site

SHARE | TWEET | LINKEDIN | PRINT | EMAIL | PRINT

New Search

Search Results for **darmerica**

CSV | Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
DARMERICA, LLC	3012339174	080233052	RELABEL, REPACK	199 Wilshire Blvd, Casselberry, Florida (FL) 32707, United States (USA)	12/31/2021

Darmerica LLC.
198 Wilshire Blvd.
Casselberry, FL 32707
Tel: 321-219-9111
Fax: 321-219-9130
www.darmerica.com

List of Employees

Khaled (Kyle) Hamza, BSc, CDR – Director of Operations and Quality
Sai Rasane, MS of Pharmacy – Quality Assistant
Christine Boykin, MS of Pharmacy – Quality Assistant
Fabrizio Mora, Bachelor of Science – Operations Team Leader
Harun Kapidzic - Operations
Zachary Carter - Operations
Kyler Price – Administrative Assistant

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 22BSBIR2752

Application/License No. _____

Darmerica LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 198 Wilshire Blvd, Casselberry, FL 32707 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Pointe Dr., 6th Floor, Brea, CA 92821 (Address of Surety), as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 20, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

22BSBIR2752

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of May, 2021.

APPLICANT/PRINCIPAL

Darmerica LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Tiah Boler, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

n/a
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MCGRIFF INSURANCE SERVICES INC
Agency Code: 22-271704

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Tiah Boler

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 22BSBIR2752
Naming Darmerica LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of June, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of May 20, 2021.

Signed and sealed in Lake Mary, Florida.

Tiah Boler

Keith D. Dalton, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler DARMERICA LLC

Physical Address 198 WILSHIRE BOULEVARD

City CASSELBERRY State FLORIDA Zip 32707

Mailing Address (if different from physical address) 198 WILSHIRE BOULEVARD

City CASSELBERRY State FLORIDA Zip 32707

Telephone (321) 219 - 9111 Website www.darmerica.com

Licensing Company Email submission@darmerica.com

Section 2: Personal Information

First KHALED Middle KYLE Last HAMZA

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

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

Mailing Address 198 WILSHIRE BOULEVARD

City CASSELBERRY State FL Zip 32707

Telephone (321) 219 - 9111 Email submission@darmerica.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials KH

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

School Name		From - To (MM/YY – MM/YY)	
RYERSON UNIVERSITY		2006-2010	
Address	City	State	Zip
350 VICTORIA STREET	TORONTO, CANADA	ONTARIO	M5B 2K3
Diploma/Degree obtained, if any			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2018 - PRESENT	[redacted] MAITLAND CROSSING WAY	ORLANDO	FLORIDA	32810
03/2017 - 11/2018	2705 MAITLAND XING WAY	ORLANDO	FLORIDA	32810
06/2016 - 03/2017	538 GREIG CIRCLE	NEWMARKET, CANADA	ONTARIO	L3Y 8S6
05/1998 - 06/2016	50 CONSTALLATION CRESCENT	RICHMOND HILL, CANADA	ONTARIO	L4C 8J3
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials KH

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

Business Name		From - To (MM/YY – MM/YY)	
DARMERICA LLC		03/2018 - PRESENT	
Business Address	**City**	**State**	**Zip**
198 WILSHIRE BOULEVARD	CASSELBERRY	FLORIDA	32707
Phone	**Title**		
(321) 219 - 9111	DIRECTOR OF OPERATIONS		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
ATTIX PHARMACEUTICALS		01/2016 - 03/2018	
Business Address	**City**	**State**	**Zip**
800-425 UNIVERSITY AVENUE	TORONTO, CANADA	ONTARIO	M5G 1T6
Phone	**Title**		
(416) 594 - 1881	ASSISTANT MANAGER OF OPERATIONS		
Description of Duties			

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below: N/A

Original Signature (electronic, copies or stamps not accepted)

May 19th 2021
Date

KH
Applicant's initials _____

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

KYLE HAMZA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/17/2021

Date

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

State of Florida, ss. County of Seminole

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

Original Signature

May 20th, 2021

Date

Subscribed and Sworn to before me this 20 day of May 2021

Elaine W Sweeney

Notary Public Signature

ELAINE W. SWEENEY
Notary Public, State of Florida
Commission# GG 921200
My comm. expires October 8, 2023

(Seal)

Applicant's Initials KW

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DARMERICA LLC

Physical Address 198 WILSHIRE BOULEVARD

City CASSELBERRY State FLORIDA Zip 32707

Mailing Address (if different from physical address) 198 WILSHIRE BOULEVARD

City CASSELBERRY State FLORIDA Zip 32707

Telephone 321) 219 - 9111 Website www.darmerica.com

Licensing Company Email submission@darmerica.com

Section 2: Personal Information

First KHALED Middle KYLE Last HAMZA

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

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

Mailing Address 198 WILSHIRE BOULEVARD

City CASSELBERRY State FL Zip 32707

Telephone (321) 219 - 9111 Email submission@darmerica.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials KH

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

School Name		From - To (MM/YY – MM/YY)	
RYERSON UNIVERSITY		2006-2010	
Address	**City**	**State**	**Zip**
350 VICTORIA STREET	TORONTO, CANADA	ONTARIO	M5B 2K3
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2018 - PRESENT	[redacted]MAITLAND CROSSING WAY	ORLANDO	FLORIDA	32810
03/2017 - 11/2018	2705 MAITLAND XING WAY	ORLANDO	FLORIDA	32810
06/2016 - 03/2017	538 GREIG CIRCLE	NEWMARKET, CANADA	ONTARIO	L3Y 8S6
05/1998 - 06/2016	50 CONSTALLATION CRESCENT	RICHMOND HILL, CANADA	ONTARIO	L4C 8J3

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
DARMERICA LLC			03/2018 - PRESENT
Business Address	**City**	**State**	**Zip**
198 WILSHIRE BOULEVARD	CASSELBERRY	FLORIDA	32707
Phone	**Title**		**Number of Employed Hours**
(321) 219 - 9111	DIRECTOR OF OPERATIONS		6000
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
ATTIX PHARMACEUTICALS			01/2016 - 03/2018
Business Address	**City**	**State**	**Zip**
800-425 UNIVERSITY AVENUE	TORONTO, CANADA	ONTARIO	M5G 1T6
Phone	**Title**		**Number of Employed Hours**
(416) 594 - 1881	ASSISTANT MANAGER OF OPERATIONS		3500
Description of Duties			

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

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

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

Continue on next page if additional space is needed.

Applicant's initials KH

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

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

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

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

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

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

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

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

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

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

Provide explanation below: N/A

Original Signature (electronic, copies or stamps not accepted)

May 19th 2021
Date

Applicant's initials KH

I, KYLE HAMZA, **certify that as the designated representative for**

DARMERICA LLC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

KYLE HAMZA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/17/2021

Date

Applicant's initials KH

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

KYLE HAMZA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/17/2021

Date

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

State of Florida, ss. County of Seminole

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

Original Signature

May 20th 2021

Date

Subscribed and Sworn to before me this 20 day of May 2021

Notary Public Signature

NOTARY PUBLIC

ELAINE W. SWEENEY
Notary Public, State of Florida
Commission# GG 921200
My comm. expires October 8, 2023
(seal)

Applicant's initials KH

4NN

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☒ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☒ No

Section 1: General Information

Facility Name: Glenmark Therapeutics Inc. USA

Physical Address: 301 Island Road, Suite A

City: Mahwah State: NJ Zip: 07430

Mailing Address (if different from physical address): 750 Corporate Drive

City: Mahwah State: NJ Zip: 07430

Telephone: 201-684-8000 Website: https://www.glenmarktherapeutics.com/

Name of Designated Representative (DR): Melvin Greene

Licensing Company Email: licensing@glenmarktherapeutics.co DR Email: licensing@glenmarktherapeutics.com

Entities the Wholesaler will Serve	Products to be Handled or Wholesaled
☐ Pharmacies	☒ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	☐ Controlled Substances
☐ Hospitals	☐ Hypodermic Devices
☒ Wholesalers	☐ Veterinary Legend Pharmaceuticals
☐ Others:	☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

6/15/2021

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Glenmark Holding SA

Corporation Name: Glenmark Therapeutics Inc., USA

Mailing Address: 750 Corporate Drive

City: Mahwah State: NJ Zip: 07430

Telephone: 201-684-8000 Email: licensing@glenmarktherapeutics.com

Contact Person Name: Sanjeev Krishan

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K**	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Sanjeev Krishan

Print Name of Authorized Person Submitting Application

Sanjeev Krishan

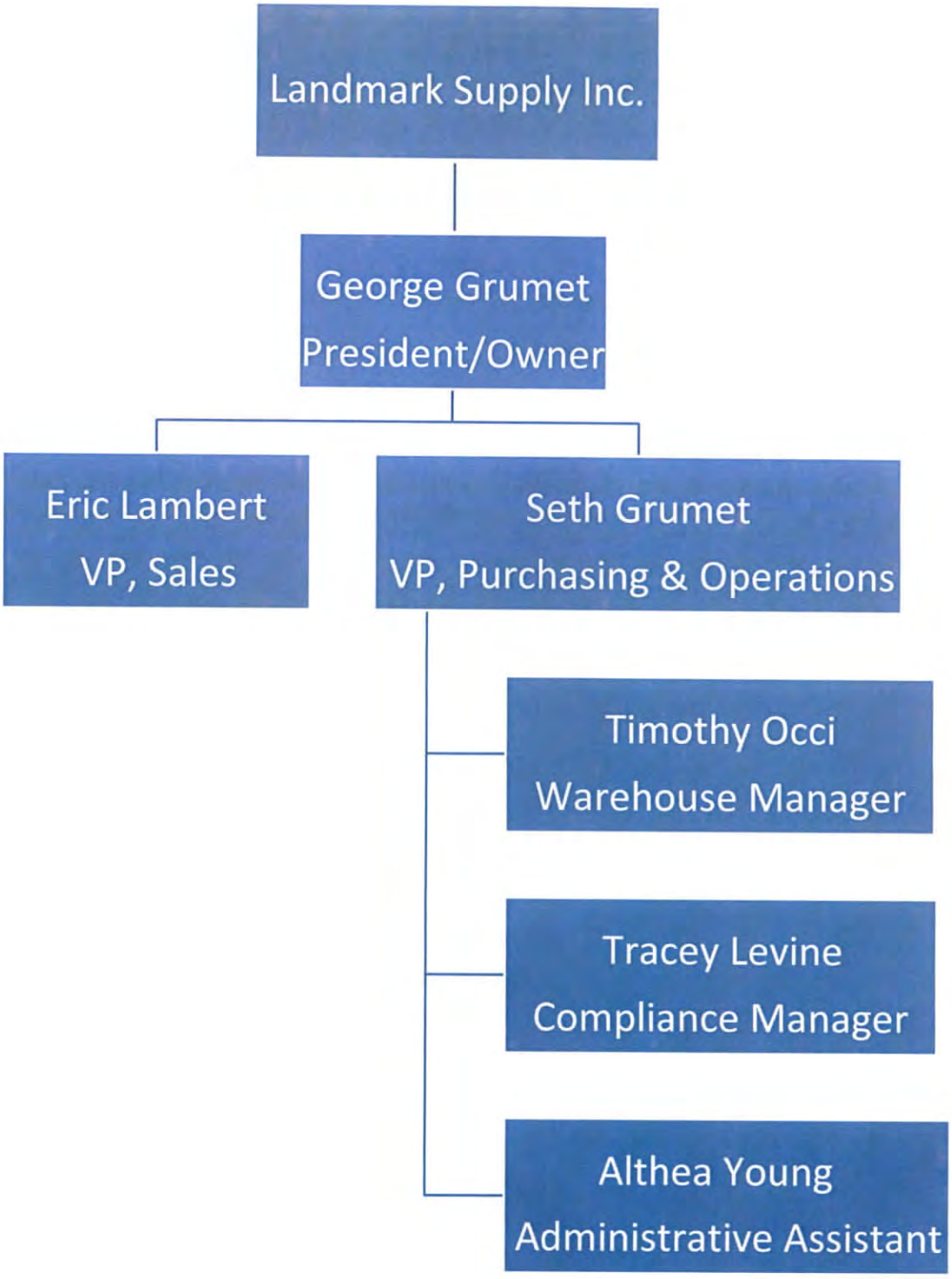
Original signature of Authorized Person (copies or stamps not accepted)

05/27/21

Date

Board Use Only	Date Received: _____	Amount: $500 Check # 13651

List of Employees for Landmark Supply



NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0742232

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

750 CORPORATE DR, STE 201-S MAHWAH, NJ 07430-
301 ISLAND RD, STE A MAHWAH,NJ 07430-

Reg. No.
5005604

GLENMARK THERAPEUTICS INC, USA
750 CORPORATE DR, STE 201-S
MAHWAH, NJ 07430-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0742232

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

750 CORPORATE DR, STE 201-S MAHWAH, NJ 07430-

Reg. No.
5005604

GLENMARK THERAPEUTICS INC, USA
750 CORPORATE DR, STE 201-S
MAHWAH, NJ 07430-

* Mailing Address

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/3/2021

Registration Number: 5005604 **Registered as:** Manufacturer and Wholesale

Name: GLENMARK THERAPEUTICS INC, USA

DBA:

Address: 750 CORPORATE DR, STE 201-S, MAHWAH, NJ 07430

Original Issue Date: 05/06/2019 **Expiration Date:** 01/31/2022

Current Issue Date: 12/01/2020

Disciplines: No

Additional Registered Addresses:
301 ISLAND RD, STE A , MAHWAH, NJ 07430

Glenmark Therapeutics Inc., USA

Ownership Information

Parent Company:

Glenmark Holding SA
Chemin de la Combeta 5
CH-2300 La Chaux-de-Fonds, Switzerland
P: +41 (32) 544 94 50

Glenmark Holding SA owns 100% of Glenmark Therapeutics Inc., USA

Company Information

Glenmark Therapeutics Inc., USA
301 Island Road, Suite A
Mahwah, NJ 07430
Phone: 201-831-0080
Website: https://www.glenmarktherapeutics.com/
E-mail: licensing@glenmarktherapeutics.com

FEIN: 26-1918753
State of Formation: DE
Date Incorporated: 06/27/2007

Officers

Sanjeev Krishan, President
Business Address: 750 Corporate Drive, Mahwah, NJ 07430
Business Phone: 201-684-8000
Percentage of Ownership: 0%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GLENMARK THERAPEUTICS INC., USA" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF JANUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GLENMARK THERAPEUTICS INC., USA" WAS INCORPORATED ON THE TWENTY-FIRST DAY OF JUNE, A.D. 2007.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4375841 8300

SR# 20210175929

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202333804

Date: 01-21-21

Glenmark Therapeutics Inc., USA

Description of Operations

Glenmark Therapeutics Inc., USA is a Self-Distributor of Glenmark Therapeutics, Inc. products. Glenmark Therapeutics Inc., USA's products are manufactured by a Contract Manufacturer and will be self-distributed to Wholesalers.

We are using the following contract manufacturer to produce our product:

Glenmark Pharmaceuticals Limited
Plot No S-7, Colvale Industrial Estate, Colvale-Bardez
Goa, India 403513
FDA Establishment No: 3004672766

Glenmark Pharmaceuticals Limited
Village Kishanpura Baddi Nalagarh Road
Baddi, Solan, Himachal Pradesh, India 173205
FDA Establishment No: 3005757050

Product Description
Glenmark Pharmaceuticals Limited manufactures Glenmark Therapeutics Inc., USA product and packages finished product. At no time does Glenmark Pharmaceuticals Limited own the product, contract with Glenmark Therapeutics Inc., USA customers, invoice, nor sell a Glenmark Therapeutics Inc., USA product. Glenmark Therapeutics Inc., USA products are not Controlled Substances.

Labeler Code:
72657

Glenmark Therapeutics Inc., USA's hours of operation are 9:00 am – 5:00pm Monday through Friday.

Donna Walters

Subject: FW: Labeler Code Request Approved

Subject: FW: Labeler Code Request Approved

Dear all,
We received the labeler code for GTI. Please see below.
Thanks to Shreyas for performing this activity in a very short period of time.

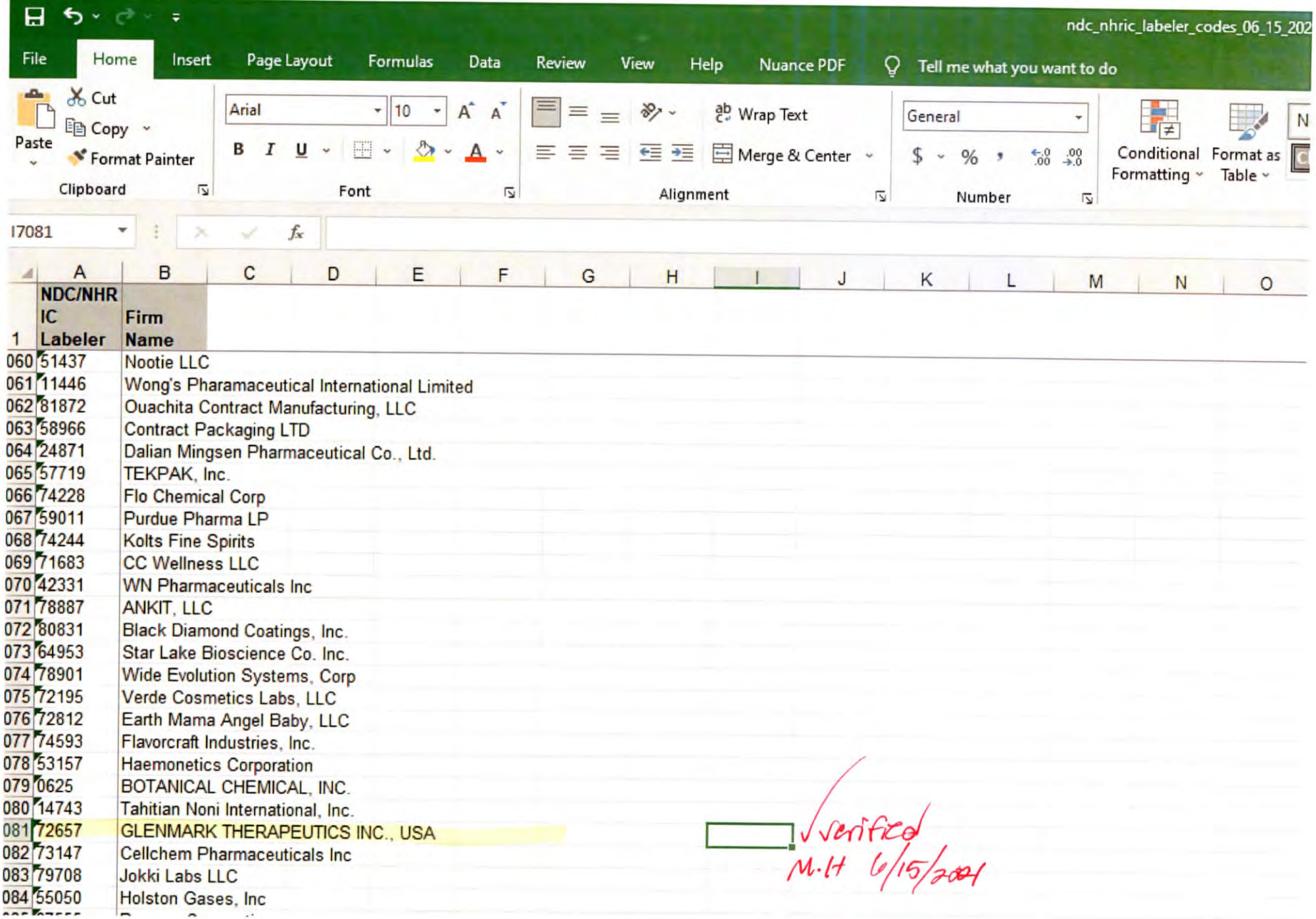
Thanks and Best Regards
Kalpana Vanam, MBA
VP, Regulatory Affairs, NA
Glenmark Pharmaceuticals Inc. USA
750 Corporate Drive Mahwah, NJ-07430
Office: 1-201-331-4282
Mobile: 1-609-510-7596
Email: kalpana.vanam@glenmarkpharma.com

From: edrls@fda.hhs.gov [mailto:edrls@fda.hhs.gov]
Sent: Thursday, November 1, 2018 3:54 PM
To: Kalpana Vanam <Kalpana.Vanam@glenmarkpharma.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 01-NOV-2018
Labeler DUNS: 969085666
Labeler Name: GLENMARK THERAPEUTICS INC., USA
Labeler Code: 72657

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**


ndc_nhric_labeler_codes_06_15_202
File Home Insert Page Layout Formulas Data Review View Help Nuance PDF Tell me what you want to do
Cut Copy Format Painter Paste
Arial 10 Wrap Text General
Merge & Center
Conditional Formatting Format as Table
Clipboard Font Alignment Number
I7081
NDC/NHRIC Labeler
Firm Name
060 51437 Nootie LLC
061 11446 Wong's Pharamaceutical International Limited
062 81872 Ouachita Contract Manufacturing, LLC
063 58966 Contract Packaging LTD
064 24871 Dalian Mingsen Pharmaceutical Co., Ltd.
065 57719 TEKPAK, Inc.
066 74228 Flo Chemical Corp
067 59011 Purdue Pharma LP
068 74244 Kolts Fine Spirits
069 71683 CC Wellness LLC
070 42331 WN Pharmaceuticals Inc
071 78887 ANKIT, LLC
072 80831 Black Diamond Coatings, Inc.
073 64953 Star Lake Bioscience Co. Inc.
074 78901 Wide Evolution Systems, Corp
075 72195 Verde Cosmetics Labs, LLC
076 72812 Earth Mama Angel Baby, LLC
077 74593 Flavorcraft Industries, Inc.
078 53157 Haemonetics Corporation
079 0625 BOTANICAL CHEMICAL, INC.
080 14743 Tahitian Noni International, Inc.
081 72657 GLENMARK THERAPEUTICS INC., USA
082 73147 Cellchem Pharmaceuticals Inc
083 79708 Jokki Labs LLC
084 55050 Holston Gases, Inc
√verified
M.H 6/15/2021

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).



Glenmark Therapeutics Inc., USA

Product List

Pregablin – labeler code - 72657

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Glenmark Therapeutics Inc. USA

Physical Address: 301 Island Road, Suite A

City: Mahwah State: NJ Zip: 07430

Mailing Address (if different from physical address): 750 Corporate Drive

City: Mahwah State: NJ Zip: 07430

Telephone: 201-684-8000 Website: https://www.glenmarktherapeutics.com/

Licensing Company Email: licensing@glenmarktherapeutics.com

Section 2: Personal Information

First: Melvin Middle: Lee Last: Greene

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

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

Mailing Address: 301 Island Road

City: Mahwah State: NJ Zip: 07430

Telephone: 2016848000 Email: licensing@glenmarktherapeutics.com

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

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

Date of Service: From: 1987 to: 1992

Military Occupation/Specialty: Captain / Brigade Logistics Officer

Branch: ☑ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials: MG

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

School Name		From - To (MM/YY – MM/YY)	
Lock Haven University			
Address	**City**	**State**	**Zip**
401 N. Fairview St.	Lock Haven	PA	17745
Diploma/Degree obtained, if any			
Bachelor of Arts, Broadcast Journalism & Speech Communication			
School Name		**From - To (MM/YY – MM/YY)**	
Central Dauphin East High School			
Address	**City**	**State**	**Zip**
626 Rutherford Road	Harrisburg	PA	17109
Diploma/Degree obtained, if any			
H.S. Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]Brighton Terrace	Parsippany	NJ	07054
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials MG

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Glenmark Pharmaceuticals			2019 - Present
Business Address	**City**	**State**	**Zip**
301 Island Road, Suite A	Mahwah	NJ	07430
Phone	**Title**	**Number of Employed Hours**	
201-684-8000	Director, U.S. Distribution, Operations	~4000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
BENJAMIN MOORE & Co.			2017 - 2018
Business Address	**City**	**State**	**Zip**
	Clifton	NJ	
Phone	**Title**	**Number of Employed Hours**	
	Director of Distribution Operations	~2000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
East Coast Warehouse			2013 - 2017
Business Address	**City**	**State**	**Zip**
1150 Polaris St	Elizabeth	NJ	
Phone	**Title**	**Number of Employed Hours**	
(908) 351-2800	Director of Customs Examination Services	~8000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
INVACARE /ASSURAMED/CARDINAL HEALTH			2011 - 2013
Business Address	**City**	**State**	**Zip**
	Cranbury	NJ	
Phone	**Title**	**Number of Employed Hours**	
	Distribution Site Manager	~4000	
Description of Duties			
See attached resume			

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

Applicant's initials MG

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials MG

I, Melvin Greene, **certify that as the designated representative for**

Glenmark Therapeutics Inc. USA,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Melvin Greene

Print Name (First, Last)

Melvin Greene

Original Signature (electronic, copies or stamps not accepted)

5/27/2021

Date

Applicant's initials MG

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

Melvin Greene
Print Name (First, Last)

Melvin Greene
Original Signature (electronic, copies or stamps not accepted)

5/27/2021
Date

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

State of NEW JERSEY, ss. County of BERGEN

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

Donna Marie Walters
Original Signature

5.27.2021
Date

Subscribed and Sworn to before me this 27 day of MAY 2021

Donna Marie Walters
Notary Public Signature

(Seal)

DONNA-MARIE WALTERS
NOTARY PUBLIC OF NEW JERSEY
Commission # 50133156
My Commission Expires 7/30/2025

Applicant's initials MG

[redacted] Brighton Terrace Parsippany, NJ 07054 - [redacted] - [redacted]

SUMMARY

Motivational leader with progressive Distribution Management experience within the Military, Medical Device, Pharmaceutical, Retail, and Customs Examination Services. Demonstrated competence in Distribution, Planning, Scheduling, Order Fulfillment, Customer Service, Inventory Management, P&L Budget Management, as well as Logistics. A strong desire to coach, counsel and develop employees at every level of the organization. Successful in creating high performing teams through the alignment of communication, motivation, training, and supervision.

Glenmark Pharmaceuticals Mahwah, New Jersey 2019 - Present
Director of Distribution Operations

Direct daily distribution operations for a staff of 3 Managers and 47 employees, supporting $420 million in sales, ensuring uninterrupted drug supply, operational excellence, quality, regulatory compliance, and customer service.

BENJAMIN MOORE & Co. Clifton, New Jersey 2017 - 2018
Director of Distribution Operations

Direct daily operations for Benjamin Moore's 300,000 Sq. Ft. Metro North East Distribution Center. Support $400 Million in sales, inventory 2.6 million gallons of paint, consisting of 2,400 SKU's; while managing a $24 million-dollar budget. Direct 75 Benjamin Moore employees, 35 Temporary employees, 3 Supervisors, as well as an Office Staff consisting of, an Environmental Health & Safety, Human Resource and Purchasing.

EAST COAST WAREHOUSE - Elizabeth, New Jersey 2013- 2017
Director of Customs Examination Services

Responsible for the CES Operations; that supports U.S. Customs Border Protection, by providing a Comprehensive Centralized Examination Services. Responsible for annual sales of $22Million with oversight of 48 employees, that includes International Longshoremen and a Customer Service Department and Internal Yard Trucking Department.

INVACARE /ASSURAMED/CARDINAL HEALTH (Acquisition) Cranbury, New Jersey 2011- 2013
Distribution Site Manager

Managed Invacare's 250,000 Sq. Ft North American Distribution Center. Supported $750 Million in regional sales, while managing a $13 Million budget. Directed, coached, and motivated 75 employees to ensure timely and accurate order fulfillment to commercial and residential customers

MEDTRONIC INC. Elizabeth, New Jersey 2010 – 2011
Distribution Site Manager

Managed all facets of Medtronic Loaner distribution program. Supported Operations staff in efficiently fulfilling customers' needs through personnel and process management and consistent interaction with the Distribution Network. Directed coached and counseled 35 Medtronic employees; managed Medtronic's relationship with 3PL provider (Excel) to ensure accurate and on-time shipment of Medtronic products

PFIZER INC. Parsippany, New Jersey 2002 – 2009
Distribution / Logistics / Operations Manager

Responsible for assembly of customer orders and new product launches. Ensured wholesale customers received orders accurately and within their allotted delivery time. Monitored and maintained product inventory. Directed, coached, and counseled 50 colleagues.

[redacted] Brighton Terrace Parsippany, NJ 07054 - [redacted]

ICF INDUSTRIES Edison, New Jersey 1996 – 2002
Operations Manager

Provided product management support to the CEO, Marketing Department, Sales Department, Vendors and U.S. Customer Brokers with respect to domestic and international manufacturing lead times and current and new product launches. Directed U.S. Customs Brokers, commercial ground carriers, vessels and transportation services ensuring product delivery within delivery cycle time. Directed, coached, and counseled 30 colleagues

WALMART - Harrisburg, Pennsylvania & Princeton, New Jersey 1992 – 1996
Operations Manager

Responsible for hiring, terminations, training, and supervision of 100+ personnel. Directed corporate, regional as well as local promotions that pertained to new products, seasonal campaigns, holiday promotions, merchandise markups, markdowns, shrink reduction and loss prevention

U.S. ARMY Fort Lewis, Washington State 1987 – 1992
Captain / Brigade Logistics Officer

Provided logistical support for the 199th Infantry Brigade, consisting of 2,000 vehicles and 5,000 soldiers during Operation Desert Storm. Directed the functional planning, coordination, procurement, and control and of movement of material, personnel and property on commercial and military transport and all facets of transportation pertaining to water, air, and highway and rail operations

EDUCATION

Lock Haven University -- Lock Haven, Pennsylvania
Bachelor of Arts, Broadcast Journalism & Speech Communication
Central Dauphin East High School, Harrisburg Pennsylvania

PROFESSIONAL DEVELOPMENT

Supply Chain Management Executive Seminar - Michigan State University
Six Sigma Green Belt - Pfizer Pharmaceuticals
Drug Enforcement Agency - Controlled Substance Distribution
Department of Transportation – Hazmat Shipping

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107308003

Application/License No. WH02643

Glenmark Therapeutics Inc., USA (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 750 Corporate Drive #201-S, Mahwah, NJ 07430 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square , Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ~~ONE HUNDRED THOUSAND~~ Twenty* ~~DOLLARS ($100,000.00)~~, for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 27, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of ~~$100,000.00~~ ** payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Five Thousand and 00/100 Dollars ($25,000.00)

**$25,000.00

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of August, 2020.

APPLICANT/PRINCIPAL
Glenmark Therapeutics Inc., USA

By: _____
Authorized Representative

SURETY COMPANY
Travelers Casualty and Surety Company of America

By: _____
Surety Company's Representative

Tanya Nguyen, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Tony Rizkalla

Witness Thomas Callaghan

DONNA-MARIE WALTERS
NOTARY PUBLIC OF NEW JERSEY
Commission # 50133186
My Commission Expires 7/30/2025

SIGNED and SEALED in the presence of:

Witness Cassandra Baez

Witness Ian Williams

Countersigned by:

Nevada Resident Agent N/A

Sworn to and subscribed before me this 10 day of SEPT, 2020

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Tanya Nguyen of **Southfield, MI** , their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law, including the following bond:

Surety Bond No.: 107308003
OR
Project Description: Pharmaceutical Wholesaler Surety Bond

Principal: Glenmark Therapeutics Inc., USA
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **6th** day of **May, 2019.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **6th** day of **May, 2019**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 27th day of August, 2020.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which this Power of Attorney is attached.

Willis Towers Watson

Telephone: 860-241-4437
Website: www.willistowerswatson.com
E-mail: melissa.stanton@willistowerswatson.com

August 27, 2020

Glenmark Pharmaceuticals Inc., USA
Attn: Donna-Marie Walters
750 Corporate Drive
Mahwah, NJ 07430

Re: ***Bond Number: 107308003***
Obligee: Nevada State Board of Pharmacy
Description: Pharmaceutical Wholesaler Surety Bond
Commission: $75.00

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice for this bond is enclosed or will be sent to you under separate cover. Please note the premium payment for this bond is due upon receipt.

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson can collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: http://www.willis.com/About_Willis/The_Willis_Way/Commission_Rates/.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Melissa Stanton

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Horizon Therapeutics USA, Inc.

Physical Address: 1 Horizon Way, N. 1220

City: Deerfield State: IL Zip Code: 60015

Telephone Number: (224) 383-3000 Fax Number: n/a

Toll Free Number: N/A

E-mail: statelicense@horizontherapeutics.com Website: www.horizontherapeutics.com

Facility Manager: Melissa Alberts

Professional qualifications and experience of facility manager:
See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)
Labeler 75987

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: _____
Address: See attached

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Barry Moze
Print Name of Authorized Person

3/29/21
Date

Board Use Only Date Processed:_____ Amount: Check # 3884118

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: see attached list of Owners and Officers

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: Barry Moze

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.



State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.004963

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2022

LICENSED WHOLESALE DRUG DISTRIBUTOR

HORIZON THERAPEUTICS USA INC
MELISSA ALBERTS
1 HORIZON WAY N 1220
DEERFIELD, IL 60015-3888

DEBORAH HAGAN
SECRETARY

CECILIA ABUNDIS
ACTING DIRECTOR

The official status of this license can be verified at www.idfpr.com

15665748

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4379668

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
HORIZON THERAPEUTICS USA INC	Deerfield, IL 60015	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004004963	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	03/18/2021	03/18/2021	12/31/2022	N

Generated on: 4/14/2021 1:30:48 PM

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HORIZON THERAPEUTICS USA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF MARCH, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HORIZON THERAPEUTICS USA, INC." WAS INCORPORATED ON THE TWENTY-SECOND DAY OF JUNE, A.D. 2005.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3989145 8300

SR# 20211084639

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202847582

Date: 03-29-21

HORIZON

OWNERSHIP INFO

Horizon Therapeutics USA, Inc.
150 Saunders Rd. Suite 400
Lake Forest, Illinois 60045

State of Formation: Delaware

Horizon Therapeutics USA, Inc. is the wholly owned subsidiary of:
Horizon Pharma Finance SARL and Horizon Therapeutics Capital Limited
150 Saunders Road, Suite 400
Lake Forest, Illinois 60045

Horizon Therapeutics plc. Is the Grandparent Company and is publicly traded on the NASDAQ (HZNP):
150 Saunders Rd. Suite 400
Lake Forest, Illinois 60045

HORIZON THERAPEUTICS USA, INC. EXECUTIVE OFFICERS

NAME	TITLE
Timothy P. Walbert	*President, CEO*
Paul Hoelscher	*EVP, Chief Financial Officer*
Jeffrey W. Sherman, M.D., FACP	*Chief Medical Officer*
Brian K. Beeler	*EVP, General Counsel*
Barry Moze	*EVP, Chief Administrative Officer*

HORIZON THERAPEUTICS USA, INC. BOARD OF DIRECTORS

NAME	
Timothy P. Walbert	*150 S. Saunders Rd. Ste 400, Lake Forest, IL 60045*
Paul Hoelscher	*150 S. Saunders Rd. Ste 400, Lake Forest, IL 60045*
Jeffrey W. Sherman	*150 S. Saunders Rd. Ste 400, Lake Forest, IL 60045*

HORIZON

Description of Operations

Horizon Therapeutics USA, Inc. ("Horizon") is a Virtual Manufacturer. Horizon's office in Deerfield, IL is a corporate office. Horizon's products, ACTIMMUNE, BUPHENYL, KRYSTEXXA, PROCYSBI, RAVICTI, RAYOS, and TEPEZZA are manufactured by contract manufacturers and distributed via a licensed third-party logistics provider (3PL). The drugs will be sold to Wholesalers, Hospitals, Pharmacies, and Physicians.

Horizon's hours of operation are 8:00am-5:00pm Central Time.

Horizon utilizes the following contract manufacturers...

ACTIMMUNE (BLA 103836)
Almac
22 Seagoe Industrial Estate
Craigavon, County Armagh BT63 5QD, United Kingdom
FDA Establishment No: 3004444888

BUPHENYL (NDA Powder 020573 | Tablet 020572)
Patheon France S.A.S.
40 Boulevard de Champaret
Bourgoin-Jallieu 38 300, France
CS 11006 38307
FDA Establishment No: 3004468553

KRYSTEXXA (BLA 125293)
Exelead Inc.
6925 Guion Rd.
Indianapolis, IN 46268
FDA Establishment No: 1000517970

PROCYSBI (NDA 203389)
Patheon Pharmaceuticals, Inc.
2110 E Galbraith Rd.
Cincinnati, OH 45237
FDA Establishment No: 1510437

HORIZON

RAVICTI (NDA 203284)
AndersonBrecon (UK) Limited
Pharos House, Wye Valley Business Park
Brecon Road, Hay-on-Wye, Hereford, HR3 5PG,
United Kingdom
FDA Establishment No: 3001670824

RAYOS (NDA 202020)
Patheon France S.A.S.
40 Boulevard de Champaret
Bourgoin-Jallieu 38 300, France
CS11006 38307
FDA Establishment No: 3004468553

TEPEZZA (BLA 761143)
Catalent Indiana, LLC
1300 South Patterson Drive
Bloomington
Indiana 47403
FDA Establishment No: 3005949964

Labeler Code: 75987

Third Party Logistics Information:
For distribution into the commercial supply channels, Cardinal SPS and Cardinal Health Specialty Pharmaceutical Services acts as Horizon's Third Party Logistics (3PL) provider to manage the storage and distribution of Horizon's product to customers throughout the United States. Cardinal Health's address is:

Cardinal SPS
15 Ingram Blvd., Suite 100
La Vernge, TN 37086

Cardinal Health dba Specialty Pharmaceutical Services
501 Mason Rd., Ste. 200
La Vergne, TN 37086

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through March 19, 2021

You have searched Finished drug products

Search Results: *'horizon therap'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product T Name
ACTIMMUNE	75987-111-11	100 ug/.5mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA103836	Horizon Therapeutics USA, Inc.	75987-111	Interferon gamma-1b	INTERFERON GAMMA-1B	HUMAN PRESCRIP DRUG
Buphenyl	75987-070-09	94 g/g	POWDER	ORAL	NDA020573	Horizon Therapeutics USA, Inc.	75987-070	sodium phenylbutyrate	SODIUM PHENYLBUTYRATE	HUMAN PRESCRIP DRUG
BUPHENYL	75987-060-08	500 mg/1	TABLET	ORAL	NDA020572	Horizon Therapeutics USA, Inc.	75987-060	sodium phenylbutyrate	SODIUM PHENYLBUTYRATE	HUMAN PRESCRIP DRUG
DUEXIS	75987-010-72	800 mg/1; 26.6 mg/1	TABLET, COATED	ORAL	NDA022519	Horizon Therapeutics USA, Inc.	75987-010	Ibuprofen and Famotidine	IBUPROFEN; FAMOTIDINE	HUMAN PRESCRIP DRUG
DUEXIS	75987-010-03	800 mg/1; 26.6 mg/1	TABLET, COATED	ORAL	NDA022519	Horizon Therapeutics USA, Inc.	75987-010	Ibuprofen and Famotidine	IBUPROFEN; FAMOTIDINE	HUMAN PRESCRIP DRUG
Krystexxa	75987-080-10	8 mg/mL	INJECTION, SOLUTION	INTRAVENOUS	BLA125293	Horizon Therapeutics USA, Inc.	75987-080	pegloticase	PEGLOTICASE	HUMAN PRESCRIP DRUG
Pennsaid	75987-040-74	20 mg/g	SOLUTION	TOPICAL	NDA204623	Horizon Therapeutics USA, Inc.	75987-040	diclofenac sodium	DICLOFENAC SODIUM	HUMAN PRESCRIP DRUG
Pennsaid	75987-040-05	20 mg/g	SOLUTION	TOPICAL	NDA204623	Horizon Therapeutics USA, Inc.	75987-040	diclofenac sodium	DICLOFENAC SODIUM	HUMAN PRESCRIP DRUG
Pennsaid	75987-040-75	20 mg/g	SOLUTION	TOPICAL	NDA204623	Horizon Therapeutics USA, Inc.	75987-040	diclofenac sodium	DICLOFENAC SODIUM	HUMAN PRESCRIP DRUG
PROCYSBI	75987-101-08	75 mg/1	CAPSULE, DELAYED RELEASE PELLETS	ORAL	NDA203389	Horizon Therapeutics USA, Inc.	75987-101	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG
PROCYSBI	75987-100-04	25 mg/1	CAPSULE, DELAYED RELEASE PELLETS	ORAL	NDA203389	Horizon Therapeutics USA, Inc.	75987-100	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product T Name
PROCYSBI	75987-140-13	75 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA213491	Horizon Therapeutics USA, Inc.	75987-140	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG
PROCYSBI	75987-140-14	75 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA213491	Horizon Therapeutics USA, Inc.	75987-140	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG
PROCYSBI	75987-145-13	300 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA213491	Horizon Therapeutics USA, Inc.	75987-145	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG
PROCYSBI	75987-145-14	300 mg/1	GRANULE, DELAYED RELEASE	ORAL	NDA213491	Horizon Therapeutics USA, Inc.	75987-145	Cysteamine bitartrate	CYSTEAMINE BITARTRATE	HUMAN PRESCRIP DRUG
Ravicti	75987-050-07	1.1 g/mL	LIQUID	ORAL	NDA203284	Horizon Therapeutics, Inc.	75987-050	glycerol phenylbutyrate	GLYCEROL PHENYLBUTYRATE	HUMAN PRESCRIP DRUG
Ravicti	75987-050-06	1.1 g/mL	LIQUID	ORAL	NDA203284	Horizon Therapeutics, Inc.	75987-050	glycerol phenylbutyrate	GLYCEROL PHENYLBUTYRATE	HUMAN PRESCRIP DRUG
RAYOS	75987-022-70	5 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-022	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-020-01	1 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-020	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-021-01	2 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-021	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-020-70	1 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-020	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-022-02	5 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-022	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-020-02	1 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-020	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-021-02	2 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-021	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-022-01	5 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-022	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
RAYOS	75987-021-70	2 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA202020	Horizon Therapeutics USA, Inc.	75987-021	prednisone	PREDNISONE	HUMAN PRESCRIP DRUG
TEPEZZA	75987-130-15	500 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761143	Horizon Therapeutics USA, Inc.	75987-130	teprotumumab	TEPROTUMUMAB	HUMAN PRESCRIP DRUG
Vimovo	75987-031-04	375 mg/1, 20 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA022511	Horizon Therapeutics USA, Inc.	75987-031	Naproxen and Esomeprazole Magnesium	NAPROXEN; ESOMEPRAZOLE MAGNESIUM	HUMAN PRESCRIP DRUG
Vimovo	75987-030-73	500 mg/1, 20 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA022511	Horizon Therapeutics USA, Inc.	75987-030	Naproxen and Esomeprazole Magnesium	NAPROXEN; ESOMEPRAZOLE MAGNESIUM	HUMAN PRESCRIP DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product T Name
Vimovo	75987-030-04	500 mg/1; 20 mg/1	TABLET, DELAYED RELEASE	ORAL	NDA022511	Horizon Therapeutics USA, Inc.	75987-030	Naproxen and Esomeprazole Magnesium	NAPROXEN; ESOMEPRAZOLE MAGNESIUM	HUMAN PRESCRIP DRUG

Showing 1 to 30 of 30 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through April 23, 2021

You have searched Finished drug products

Search Results: *'75987'*

Back to Search Page | Search Again

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
ACTIMMUNE	75987-111-11	100 ug/.5mL	INJECTION, SOLUTION	SUBCUTANEOUS	BLA103836	Horizon Therapeutics USA, Inc.	75987-111	Interferon gamma-1b	INTERFERON GAMMA-1B	HUMAN PRESCRIPTION DRUG	12/01/2013	N/A	BLA	12 VIAL, SINGLE-USE in 1 CARTON (75987-111-11) > .5 mL in 1 VIAL, SINGLE-USE (75987-111-10)
Buphenyl	75987-070-09	.94 g/g	POWDER	ORAL	NDA020573	Horizon Therapeutics USA, Inc.	75987-070	sodium phenylbutyrate	SODIUM PHENYLBUTYRATE	HUMAN PRESCRIPTION DRUG	04/30/1996	N/A	NDA	1 BOTTLE in 1 CARTON (75987-070-09) > 250 g in 1 BOTTLE
BUPHENYL	75987-060-08	500 mg/1	TABLET	ORAL	NDA020572	Horizon Therapeutics USA, Inc.	75987-060	sodium phenylbutyrate	SODIUM PHENYLBUTYRATE	HUMAN PRESCRIPTION DRUG	05/13/1996	N/A	NDA	1 BOTTLE in 1 CARTON (75987-060-08) > 250 TABLET in 1 BOTTLE
DUEXIS	75987-010-72	800 mg/1; 26.6 mg/1	TABLET, COATED	ORAL	NDA022519	Horizon Therapeutics USA, Inc.	75987-010	Ibuprofen and Famotidine	IBUPROFEN; FAMOTIDINE	HUMAN PRESCRIPTION DRUG	12/05/2011	N/A	NDA	9 BLISTER PACK in 1 CARTON (75987-010-72) > 3 TABLET

Verified M. Lt

Melissa S. Alberts

Results driven, dynamic leader improving quality and operational performance in a variety of key leadership roles. Proven ability to implement change and drive continuous improvement within key Quality functions through development of key performance indicators that aid decision-making, promote sustainability and increase productivity. Excel at developing and mentoring staff and creating positive work environment. Highly effective communicator and strategic planner.

❖ **Horizon Therapeutics, Lake Forest, IL** **Nov 2017–Current**
Executive Director, Quality **Oct 2019–Current**
Executive level quality leader responsible for Lake Forest site clinical and development quality activities. Directly responsible for quality oversight of development and clinical projects, as well as providing technical input on strategy. Responsible for all company GxP training, establishing a strategy and platform for clinical, development, distribution and Pharmacovigilance training. Responsible for Quality oversight for drug storage and distribution licensing. Leading inspection readiness activities for the Lake Forest site. Directly responsible for vendor management and oversight activities.

Senior Director, Quality **Nov 2017–Oct 2019**
Quality leader responsible for driving improvements in reliable supply for commercial products, responsibility for development products, and establishing Quality System infrastructure necessary for long-term quality management, release and distribution of all commercial and development products. Activities include data creation and analysis, risk assessment execution and remediation, regulatory audit preparation and management, vendor management, investigation management, and creation and implementation of new processes, policies and procedures.

- Successfully managed Prior Approval Inspections at 2 CMOs for positive recommendation.
- Created and implemented new Stability Program for commercial and development products.

❖ **Fresenius Kabi, Melrose Park, IL** **May 2016–Nov 2017**
Director, Quality Operations (Site Head)
Site Head of Quality for sterile injectable manufacturing – aseptic and lyophilized filling operations. Responsibility for Quality Assurance, Quality Systems, Regulatory agency communication, Audit Management, Quality Operations and Quality ownership of $250M+ facility expansion activities.

- Established and implemented improvements to drive organizational effectiveness, compliance remediation, and harmonized continuous improvement program within the US region.
- Designed and implemented new Quality Operations organizational structure.
- Drove regional alignment of quality processes across 4 sites.

❖ **Catalent Pharma Solutions, Woodstock, IL** **Jun 2006–May 2016**
Director, Quality Assurance (Site Head) **Apr 2014–May 2016**
Site Head of Quality responsible for Quality Assurance, Quality Systems, Validation, Regulatory, Analytical Services, Microbiology, Training and Inspection Management (120+ personnel), inclusive of all site and distribution licensing for the portfolio of prescription drug products. Established and maintained strategic goals for continuous improvement of site and team performance. Member of the Site Leadership Team, partnering on new product introductions and directing 24/7 sterile operations. Primary point of contact with all regulatory bodies, responsible for all regulatory inspections.

- Drove site quality improvements: 30% reduction in deviations, 90% reduction in overdue training, 100% reduction in overdue audit responses, 37% reduction in QA spend, while improving compliance position and regulatory inspection outcomes. Zero observations from FDA and ISO in 2015.

Manufacturing Quality Assurance (MQA) Manager **Mar 2012–Apr 2014**
Actively led and managed quality operations for 36 sterile filling lines, 3 packaging lines, 25 active clients and 30-35 active R&D clients, while managing 4 shifts, 24/7 personnel responsible for quality testing and environmental monitoring. Continuously drove improvements while providing QA oversight for the manufacture of all sterile pharmaceutical products. Primary QA Manager for all inspection activities.

- Batch release improvements: created visual management system for all batch records, driving 100% improvement in batch review compliance, and 35% reduction in review cycle time.
- Quality operations improvements: 50% reduction in quality operations management headcount while driving 75% reduction in department deviations, created visual management system for quality samples, drove integration of environmental monitoring team into Quality operations.

Quality Assurance Supervisor **Dec 2011–Mar 2012**
Managed batch release team responsible for all commercial, clinical and development drug and device product releases.

- Created positive work environment and team focus through implementation of job descriptions, mission/vision statements and key performance indicators to track and drive team performance.

Quality Assurance Product Manager **Sep 2008–Dec 2011**
Successfully managed 10+ clients through creation of high functioning, positive relationships. Performed review of all client documents - deviations, CAPAs, change controls, qualifications, annual product reviews. Created quality assurance agreements for new clients, client management tools to manage client deliverables, and standard client business review materials. Led all client regulatory interactions, (i.e. field alert reports) investigations and communication. Performed vendor audits to support clients.

- Partnered with top client to close site concerns leading to new contract and new suite build out.

Microbiologist **Jun 2006–Sep 2008**
Mastered skills in pharmaceutical microbiology testing to support manufacturing, from raw material to release testing, including utility and environmental monitoring.

- Drove cost-savings and efficiencies through onboarding of new technologies and suppliers.
- Improved compliance of lab through gap analyses and standardizing documentation processes.

❖ **Pharmaceutical Systems, Inc., Mundelein, IL** **May 2004–Jun 2006**
Research Scientist II/Team Lead
Quality consultant for pharmaceutical facilities, responsible for creating controlled documents, qualification documents, microbiological testing, method validation, sterilization validation, facility environmental monitoring, data analysis and delivering training.

❖ **Midwestern University, Downers Grove, IL** **Jun 2003–May 2004**
Research Technician studying impact of thyroxin on retinal pigment epithelial cells

Education
Bachelor of Science in Biology, Illinois State University

Professional Activities and Memberships

- Parenteral Drug Association (PDA) 7+ year member
- Healthcare Businesswomen's Association (HBA) member
    - Board Member on HBA Executive Engagement Programming Board
- International Society for Pharmaceutical Engineering (ISPE) member
- Chair for Horizon Women@ Business Resource Group

Regulatory Experience

- Participated in >100 client and regulatory inspections – direct host expertise including FDA, MHRA, HPRA, ANVISA, ISO, Russian Pharm Standard, Health Canada
- Primary contact with FDA, EU, ISO and all regulatory bodies for facility oversight and inspection management

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0797352

Application/License No. _____

Horizon Therapeutics USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 Horizon Way Deerfield, IL 60015 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4200 Six Forks Rd, Suite 1400 Raleigh, NC 27609 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 14, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 14th day of April, 2021.

APPLICANT/PRINCIPAL

Horizon Therapeutics USA Inc.

_____
Authorized Representative

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SURETY COMPANY

Harco National Insurance Company

_____
Surety Company's Representative

Julie Karnes, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness Lori Wright

_____
Witness Bonnie Rice

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Bond # 0797352

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

KATHY L. DELGRECO, RACHEL A. CHAVERIAT, MICHELLE LUTE-HEATHERLY, JESSICA FREDERICK, JULIE KARNES, BONNIE L. RICE, MARY Y. VOLMAR, ANDREA ALLMAN, JOY M. WILLIAMS, CAROLYN E. WHEELER, VICKI NOBINGER, LORETTA M. JONES, SANDY MCELHANEY, THELMA M. LETT

Knoxville, TN

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2019

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1984 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2019, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC No. 50079016 NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, April 14, 2021

A00795

Irene Martins, Assistant Secretary

Lori A Wright

MARSH

Marsh USA Inc.
1111 Northshore Drive Suite N-550
Knoxville, TN 37919

lori.a.wright@marsh.com
www.marsh.com

April 15, 2021

Mara Wachholder
Horizon Therapeutics
150 S. Saunders Rd.
Lake Forest, IL 60045

Subject: New Bond

Principal: Horizon Therapeutics USA Inc.
Obligee: Nevada State Board of Pharmacy
Bond Description: Pharmaceutical Wholesaler Bond
Bond Amount: $100,000.00
Bond Number: 0797352
Surety Name: Harco National Insurance Company
Bond Effective Date: April 14, 2021

Dear Mara:

Enclosed is the above-referenced bond in response to your request dated 04/14/2021. The bond is based on the information we received with the request. Please recheck the bond for accuracy, and have it signed, sealed, and forwarded to the Nevada State Board of Pharmacy for acceptance and filing.

In the event you do not accept and file the bond with the obligee, please return this original document to Marsh so we can notify the surety company that the bond was not accepted and filed; otherwise, the surety company will process a premium billing for the bond.

You will be receiving our invoice for this transaction in the amount of $1,500.00. Marsh will receive 30.00% of this amount from the surety company. Unless otherwise notified, Marsh will receive the established commission on all subsequent billings for as long as the bond remains in force. Your signature on the bond and payment of our invoice constitutes your agreement to our compensation by the surety for this bond.

If you have any questions, please feel free to contact me. Thank you for allowing Marsh to service your surety needs.

Sincerely,

Lori A Wright,
Enclosure

HORIZON

April 20, 2021

Via Fed Ex

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV 89509

To Whom It May Concern:

On behalf of Horizon Therapeutics USA, Inc. ("Horizon"), attached is Horizon's application for Wholesale Drug Distributor.

Horizon believes science and compassion must work together to transform lives. Our mission to deliver medicines for rare, autoimmune and severe inflammatory diseases and provide compassionate support comes from our strong and simple philosophy to make a meaningful difference for patients and communities in need.

Horizon is a "Virtual Manufacturer" whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Horizon's office. Horizon's products are not controlled substances. Accordingly, Horizon is not required to obtain a DEA registration.

I hope this narrative is helpful as you review Horizon's application. If you have a question regarding this application, please contact me at 614-370-2801 or via email at stacie.borngrebe@twolabs.com. Please also address all written communication to me. My address is 2123 English Turn Dr. Grove City, OH 43123.

Thank you in advance for your consideration.

Stacie Borngrebe
Licensing Analyst
PharmaLicense

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Juno Therapeutics Inc.

Physical Address: 1522 217th Pl, SE

City: Bothell State: WA Zip Code: 98021

Telephone Number: 206-582-1600 Fax Number: _____

Toll Free Number: _____

E-mail: karlika.cintron@bms.com Website: www. junotherapeutics.com

Facility Manager: Karlika Cintron-Garcia

Professional qualifications and experience of facility manager: See attached Resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☑ Hospitals ☑ Wholesalers
☑ Other: Infusion Clinic

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Lonza Group, AG: Contract Manufacturer
Address: 8066 EL Rio St., Houston TX 77054

Name: Perkin-Elmer: Raw Material Supplier
Address: 68 Elm st., Hopkinton, MA 01748

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Katherine R. Kelly

Print Name of Authorized Person

2/5/21

Date

Board Use Only	Date Processed: ✓5/14/2021	Amount: 500 Check # 639589

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Bristol Myers Squibb

Mailing Address: 430 E. 29th Street, 14th Floor

City: New York State: NY Zip: 10016

Telephone: 212-546-4000 Fax: _____

Contact Person: Karlika Cintron-Garcia

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Bristol Myers Squibb - 430 E. 29th Street, 14th Floor , New York, NY 10016 - 100% ownership
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. 0

3) What was the price paid per share? 0

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

730

Washington State Department of Health

This organization

Juno Therapeutics Inc.

is authorized by RCW 18.64 to have a

Pharmaceutical Manufacturer License

Operated by: **Juno Therapeutics Inc.**

Located at: **Attn: David M. Chu**
1522 217th Pl SE
Bothell, WA 98021-7617

Secretary

Status
ACTIVE

Credential Number
PHMF.FX.60612017

Effective Date
10/01/2020

Expiration Date
09/30/2021

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "JUNO THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-NINTH DAY OF MARCH, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5378373 8300

SR# 20211087251

Authentication: 202848861

Date: 03-29-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Juno Therapeutics, Inc.

Nevada Business Identification # NV20212019758
Expiration Date: 02/28/2022

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/18/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202102181439676
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

FOREIGN CORPORATION (80) QUALIFICATION

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Juno Therapeutics, Inc.** did on **02/18/2021** file in this office its Qualification to do Business in this State and is now on file and of record in the office of the Nevada Secretary of State, and further, that said corporation is at the date of this Certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/18/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202102181439674
You may verify this certificate online at http://www.nvsos.gov

Facility Search

DOH Home | Facilities Home

Search

Search

Facility Information

NEW SEARCH RESULTS

Facility Name: Juno Therapeutics Inc.
Address: Attn: David M. Chu, 1522 217th Pl SE, Bothell, WA, 98021-7617
Owner's Name: Juno Therapeutics Inc.
License #: PHMF.FX.60612017
Facility Status: ACTIVE
Facility Type: Pharmaceutical Manufacturer License
License Expires On: 09/30/2021

If you find any errors in this description, please complete the Feedbackform and send it to us.

Contact Us

Agency Contacts
Locations and Directions
Consumer Assistance and Support
Email Consumer Assistance and Support
Main: (360) 236-4700
Fax: (360) 236-4818

Social Media

Notices

Privacy Notice
Copyright Statement

Powered By

Alternate Format Requests

For people with disabilities, Web documents in other formats are available on request. To submit a request, please contact Consumer Assistance and Support.

v2.4.0

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Juno Therapeutics**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Juno Therapeutics, Inc.	3011834594	079941307	ANALYSIS; LABEL; MANUFACTURE; PACK;	1522 217th Pl, SE, Bothell, Washington (WA) 98021, United States (USA)	12/31/2021

Showing 1 to 2 of 2 entries
Previous1Next
Data Current through: Friday, Nov 13, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drug Establishments Current Registration Site

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

New Search

Search Results for **Juno**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Juno Therapeutics, Inc.	3010932912	079290042	ANALYSIS;	400 Dexter Avenue N Ste 1200, Seattle, Washington (WA) 98109, United States (USA)	12/31/2021
Juno Therapeutics, Inc.	3011834594	079941307	ANALYSIS; LABEL; MANUFACTURE; PACK;	1522 217th Pl, SE, Bothell, Washington (WA) 98021, United States (USA)	12/31/2021

Showing 1 to 2 of 2 entries

Previous 1 Next

Data Current through: Wednesday, Mar 31, 2021

Return to Drug Firm Annual Registration Status Home Page

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Verified
M. It.
3/31/21

Corporate Officer Information

Juno Therapeutics Inc.
1522 217th Pl, SE
Bothell, Washington (WA) 98021
FEIN: 46-3656275

Bristol Myers Squibb Company – Parent Company

Address: 430 E. 29th Street, 14th Floor New York, NY 10016

Sophia Park – President

Business Address: 100 Nassau Park Boulevard, Princeton NJ 08540
Business Phone: 609- 419-5000
Home Address: [redacted] Kings Court, Mountainside, NJ 07092
Home Phone: N/A
Ownership: 0%
Date of Birth: [redacted]
SSN:

Katherine R. Kelly – Secretary

Business Address: 430 E. 29th Street, 14th Floor New York, NY 10016
Business Phone: 212-546-4000
Home Address: [redacted] Irving Avenue, Englewood Cliffs, NJ
Home Phone: N/A
Ownership: 0%
Date of Birth: [redacted]
SSN:

Jeffrey Galik – Sr. Vice President, Treasurer

Business Address: Route 206 & Province Line Road, Princeton, NJ 08543
Business Phone: 609-252-3144
Home Address: [redacted] Manners Road, Ringoes, NJ 08551
Home Phone: [redacted]
Ownership: 0%
Date of Birth: [redacted]
SSN:

From: Cintron, Karlika
To: Campbell, Teresa
Subject: NDC Information
Date: Tuesday, November 10, 2020 3:25:28 PM
Attachments: image001.png
image002.png

Hi Teresa,

Per request, this is the NDC information. Thank you.

BREYANZI consists of genetically modified autologous T cells, supplied in vials as separate frozen suspensions of each CD8 component (NDC 73153-901-08) and CD4 component (NDC 73153-902-04). Each CD8 or CD4 component is packed in a carton containing up to 4 vials, depending upon the concentration of the cryopreserved drug product CAR-positive viable T cells. The cartons for each CD8 component and CD4 component are in an outer carton (NDC 73153-900-01). BREYANZI is shipped directly to the cell lab or clinical pharmacy associated with the infusion center in the vapor phase of a liquid nitrogen shipper. A Release for

Karlika Cintrón
Sr. Manager | Supply Chain
Cell Therapy Development Operations (CTDO)
OLA Washington Chapter Co-lead
OLA (Organization for Latino Achievement)

Office +1 206.829.3803
Mobile +1 919.906.2200

Bristol Myers Squibb
1522 217th PL SE
Bothell, WA 98021 USA

Bristol Myers Squibb

This message (including any attachments) may contain confidential, proprietary, privileged and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

KARLIKA CINTRON

[redacted] Callow Rd • Lake Stevens, WA 98258

OVERVIEW Production Management and Quality Assurance Professional with 23+ years of experience in pharmaceutical organizations.

AREAS OF EXPERTISE

- Production/QA Management
- Operational excellence
- Quality Risk Management
- Facility/Product start up
- Investigations / Technical Reports
- FDA, EUDRALEX, EPA, & OSHA Regulations and Procedure

EXPERIENCE

Juno Therapeutics, a Bristol Myers Squibb Company Bothell , WA

Supply Chain Senior Manager- Compliance & Operations **Compliance & Operations** 2017-Present

Manage and support the site Supply Chain (SC) departmental training, cGMP documentation, compliance regarding Change Control, Deviation and CAPA completion, metrics development, as well as Operational Excellence and process improvement initiatives. Provides indirect leadership to the warehouse, scheduling and ERP teams and serves as a primary connection to the external corporate Supply Chain functions in procurement, supplier management, and planning. Collaborates with internal and external stakeholders to meet objectives and goals.

QA Operations Senior Manager- Deviation Management

Lead the Quality Deviations Investigation Team, establishing processes and procedures and providing guidance cross-functionally at the JuMP site to ensure the written investigation reports contain the technical merit and thoroughness to meet all regulatory expectations. Ensure Deviations Team can provide QA SME oversight of GMP deviation investigations during regulatory inspections. Train the trainer for the Cell Therapy Operations Investigation Program. Mentor other Quality and Site personnel and enable their individual growth with respect to deviation investigation completeness and GMP expectations. Contribute to the development and execution of Juno's PLI and commercialization readiness plan at JuMP. Lead Cross Functional Optimization Group to identify areas of improvements within the deviation business process.

QA Operations Manager

Lead and manage the day to day activities of quality assurance operations personnel and ensure the efficiency and effectiveness of all on-site quality operations activities. Mentor Quality personnel and enable their individual growth. Support QA compliance activities such as Change Control impact assessments, deviation input including root cause determination, and CAPA deliverables. Assure product quality is consistent with established standards and in compliance with regulatory and industry standards.

Merck Manufacturing Division Wilson, NC

QA Manager 2010-2017

Lead the Deviation Management system for the site and supporting root cause analysis, corrective action identification, and recommendation of affected material disposition. Primary source of advice, guidance and input regarding quality issues for production personnel and Merck divisional and inter-site customers. Participates in internal/external GMP audits and regulatory inspections (domestic and international).

QO Specialist

Authorized Release Person (ARP) for International Markets. Support new products launch as a Quality Operations representative. Participate in Regulatory Inspections for US and International markets. Control of material, defect resolution, primary packaging component and print inspection and release, Supplies Inspection statistical sampling and testing per Quality Standard, Copyreading pre/post press items, bulk release, finished product release, batch record review, investigations, and other Quality Assurance related functions.

Quality Auditor (Contingent employee) 2009-2010

Sampling, inspect and release of incoming packaging components and printed components. Perform quality tests to bottles, foil, film, caps, cartons, labels, patients and physicians inserts, and bulk material to be used in the packaging area. Complete data sheets for all production supplies and input into Trackwiswe.

Schering-Plough Las Piedras, P.R.

Sr. Manufacturing Supervisor 2007-2009

Lead Operations strategy as part of the facility & product start up. Support the new product introduction for Small Scale Facility. Responsible for overall production operations in designated area, developing production plans to ensure on time compliance with production requirements schedule, as well as orchestrate and coordinate all activities in the area, including manufacturing, maintenance, quality and personnel related activities. Makes necessary changes to promote operation efficiency and identify continuous improvement opportunities.

Warner Chilcott — Fajardo, P.R.
Process Technologist — 2004-2007

Preparing, protocols, reviewing and executing equipment validation. Evaluating the processes for new and/or existing products to identify opportunities of improvement to prepare and complete the necessary studies or data collection. Supporting organization initiatives to achieve the goal. Assisting in investigations and problem solving providing writing mentorship. Acting as an advisor to the manufacturing personnel concerning processes.

Manufacturing Supervisor (Special Assignment)

Ensure success of operations on a day to day basis. Directing, planning, organizing and controlling operations. Primarily responsible for ensuring required levels of safety, quality and productivity are met. Support manufacturing operations by working effectively within the management team to execute goals, objectives, and tasks to achieve desired results. Provide leadership and technical oversight to staff members and junior personnel. Provide cross functional coordination and issue resolution across manufacturing operations, other groups and / or projects.

Valeant (Former ICN Dutch Holdings B.V.) — Humacao, P.R.
Operational Excellence - Black Belt — 2002 to 2004

Identifying opportunity through baselines and create project plans. Leading teams of experts and doers. Motivating trough their enthusiasm. Deploying "Voice of the Lean-Six Sigma (L6σ) process" throughout the organization. Training project teams on L6σ tools and Techniques. Optimizing processes; continually improving the business. Reviewing L6σ project progress and direction. Delivering the results; contributing to the KPIs. Planning and delivering project team recognition for a job well done.

Process Supervisor

Supervising weighing, granulation, compression, coating and printing operators. Conducting investigations regarding processes and safety. Determining manpower requirements, assigning and supervising personnel, to ensure that the product is manufactured within quality, regulatory, and safety standards. Determining and evaluating the material level, machines, raw materials and equipment needed to perform an efficient operation. Identifying opportunities of improvements in the processes. Coordinating and supporting validation activities. Preparing and discussing performance evaluations.

Process Assurer

Investigating manufacturing process deviations, stability failures, complaints and rejections. Relating and comparing data from different sources, identifying issues, securing relevant information, and identifying relationships and trends. Follow up on all investigations to assure action items and corrective actions are completely and implemented. Discussing investigation findings and manufacturing related documentation with affected areas. Developing and revising SOP for manufacturing area. Providing orientation / training according to investigation results.

McNeil Consumer Healthcare — Las Piedras, PR
Manufacturing Supervisor — 1996 to 2002

Coordinating daily activities such as: plan execution and equipment maintenance. Conducting investigations regarding processes and safety. Determining and evaluate the material level, machines, raw materials and equipment needed to perform an efficient operation. Select, employ, evaluate, supervise, enforce policies, develop and recognize employees. Developing and lead projects to improve safety and quality. Maintaining effective communication with internal customers. Coordinating and supporting validation activities.

QA & Product Disposition Supervisor

Coordinating and Supervising Batch Record Reviewers, Product Disposition Coordinators, QA administrative personnel, QA Auditors, QA Technicians at Product Disposition, Document Control, Label Room, Incoming Area, and Packaging lines. Approving investigations and Action Notices. Developing, creating and reviewing SOPs. Developing and implementing a Line Clearance Program and Total Quality Management new approach program. Participating in Planning and Tactical meetings. Preparing and discuss performance evaluations.

Quality Systems Specialist

Monitoring, reviewing, analyzing and approving Quality Systems such as Change Control, Annual Product Review, Calibration and Validation. Evaluating systems, project's documentation and review SOPs to assure compliance with current procedures and FDA regulations.

Compliance Auditor & QA Batch Auditor

Making scientific, compliance and regulatory judgment of process and analytical validation reports and related documentation. Handling effective FDA inspections as an Inspection Team member. Coordinating and participating in manufacturing auditing processes. Participating in Process Excellence projects (Cycle Time Reduction and Batch Record Re-design). Handling and follow up of corrective actions established on process deviations, corporate audits, and FDA inspections. Assist the Consumer Complaint Specialist in Consumer Complaint investigations

CONTINUOS EDUCATION / SKILLS

- Spanish/English - Professional Oral and Written
- Computer Literacy: SAP, Trackwise, Excel, Power Point, Word, Internet research

EDUCATION

POLYTECHNIC UNIVERSITY OF PUERTO RICO — Río Piedras, PR
MBA-Environmental Management — 2001

UNIVERSITY OF PUERTO RICO — Río Piedras, PR
BS- Natural Sciences — 1997

Proof of Surety

GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: License & Permit

Bond No. : 107398304

Dated effective: 4/16/2021
(MONTH, DAY, YEAR)

executed by: Juno Therapeutics, Inc. , **as Principal,**
(PRINCIPAL)

and by: Travelers Casualty and Surety Company of America , **as Surety,**
(SURETY)

and in favor of : Nevada State Board of Pharmacy .
(OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to adding

Additional Principal Location
1522 217TH PL SE BOTHELL, WA 98021

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 5/14/2021
(MONTH, DAY, YEAR)

Signed and Sealed 5/13/2021
(MONTH, DAY, YEAR)

Juno Therapeutics, Inc.
PRINCIPAL

BY: _____
TITLE

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD, CONN.

Travelers Casualty and Surety Company of America
SURETY

BY: _____
Bethany Stevenson, ATTORNEY-IN-FACT

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Bethany Stevenson,** of **Hartford, Connecticut,** their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **3rd** day of **February, 2017.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **3rd** day of **February, 2017**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

In Witness Whereof, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

Marie C. Tetreault
Marie C. Tetreault, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 13th day of May , 2021

Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which the power is attached.

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107398304

Application/License No. _____

Juno Therapeutics, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 556 Morris Ave, S12 Suite 3-4, Summit, NJ 07901 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square , Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 16, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of April, 2021.

APPLICANT/PRINCIPAL
Juno Therapeutics, Inc.

By: _____
Authorized Representative

SURETY COMPANY
Travelers Casualty and Surety Company of America

By: _____
Surety Company's Representative

Joshua Sanford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Eric Strba

_____
Witness Kathryn Pryor

Countersigned by:

_____
Nevada Resident Agent
Aimee R Perondine, NV Non-Resident Agent License No. 3134182

TRAVELERS	**Travelers Casualty and Surety Company of America** **Travelers Casualty and Surety Company** **St. Paul Fire and Marine Insurance Company** **Farmington Casualty Company**

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Joshua Sanford** of **Short Hills, NJ** , their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law, including the following bond:

Surety Bond No.: 107398304
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Juno Therapeutics, Inc.
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **6th** day of **May, 2019.**

State of Connecticut

By:_____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **6th** day of **May, 2019**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 16th day of April, 2021.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which this Power of Attorney is attached.

IMS Health & Quintiles are now IQVIA™

State Services
1025 Boulders Parkway
Suite 301
North Chesterfield, VA 23225
iqvia.com

Via Federal Express



March 25, 2021

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

Dear Ladies and Gentlemen:

Enclosed, you will find an initial application along with Check in the amount of $500.00 and required attachments on behalf of our client Juno Therapeutics Inc., located at 1522 217th PL, SE, Bothell, WA 98021 who is applying for licensure in your state as an Out-of-State Wholesaler.

If you have any questions, please call me toll-free at (888) 590-9954 ext. 5079 or email me at Teresa.campbell1@iqvia.com.

Thank you for your time and assistance in this matter.

Sincerely,

Teresa Campbell

Teresa Campbell
State Services

4QQ

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Rev (04/01/2021)

Where is the facility located? ☐ Nevada ☑ Out-of-State

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

Is your facility a reverse distributor? ☐ Yes ☑ No

Section 1: General Information

Facility Name: Lanamark Supply Inc

Physical Address: 440 Raritan Avenue

City: Highland Park State: NJ Zip: 08904

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 732-769-5008 Website: www.lanamarksupplyinc.com

Name of Designated Representative (DR): Eric Lambert

Licensing Company Email: lanamarksupply@lanamarksupplyinc.com DR Email: eric@lanamarksupplyinc.com

Entities the Wholesaler will Serve	Products to be Handled or Wholesaled
☑ Pharmacies	☑ Legend Pharmaceuticals, Supplies or Devices
☐ Practitioners	☐ Controlled Substances
☑ Hospitals	☐ Hypodermic Devices
☐ Wholesalers	☐ Veterinary Legend Pharmaceuticals
☐ Others:	☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Received. 6/8/2021

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Perrigo
Address: 515 Eastern Ave City: Allegan State: MI Zip: 49010
Name: Mastels
Address: 3000 Pharma Way City: Mason State: OH Zip: 45036
Name: Sola Pharmaceuticals
Address: 18169 E Petroleum Dr City: Baton Rouge State: LA Zip: 70809
Name: Real Value
Address: 5100 Commerce Way City: San Antonio State: TX Zip: 78218

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation

State of Incorporation: New Jersey
Parent Company (if any):
Corporation Name: Landmark Supply Inc
Mailing Address: 440 Raritan Avenue
City: Highland Park State: NJ Zip: 08904
Telephone: 7327695008 Email: landmarksupply@landmarksupply.com
Contact Person Name: George Brunet

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K**	✓			
• **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

GEORGE GRUMET

Print Name of Authorized Person Submitting Application

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

5/21/24

Date

Board Use Only	Date Received: 6/16/2024	Amount: $500 Check # 006347



George Grumet
Owner – 80%
DOB: [redacted]
SSN: [redacted]
Home address:
[redacted] Phillips Road
Edison, NJ 08817

Seth Grumet
Owner – 20%
DOB: [redacted]
SSN: [redacted]
Home address:
[redacted] Kings Court
Marlboro, NJ 07746

Landmark Supply Inc.
440 Raritan Avenue
Highland Park, NJ 08904
Fed ID #45-2856992

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

LANDMARK SUPPLY INC
0400433328

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on August 03, 2011.

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

I further certify that the registered agent and office are:

GEORGE GRUMET
17 PHILLIPS RD.
EDISON, NJ 08817

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 25th day of May, 2021

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6119417483

Verify this certificate online at

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

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 5/25/2021

Registration Number: 5004238 **Registered as:** Wholesale

Name: LANDMARK SUPPLY

DBA: LANDMARK SUPPLY

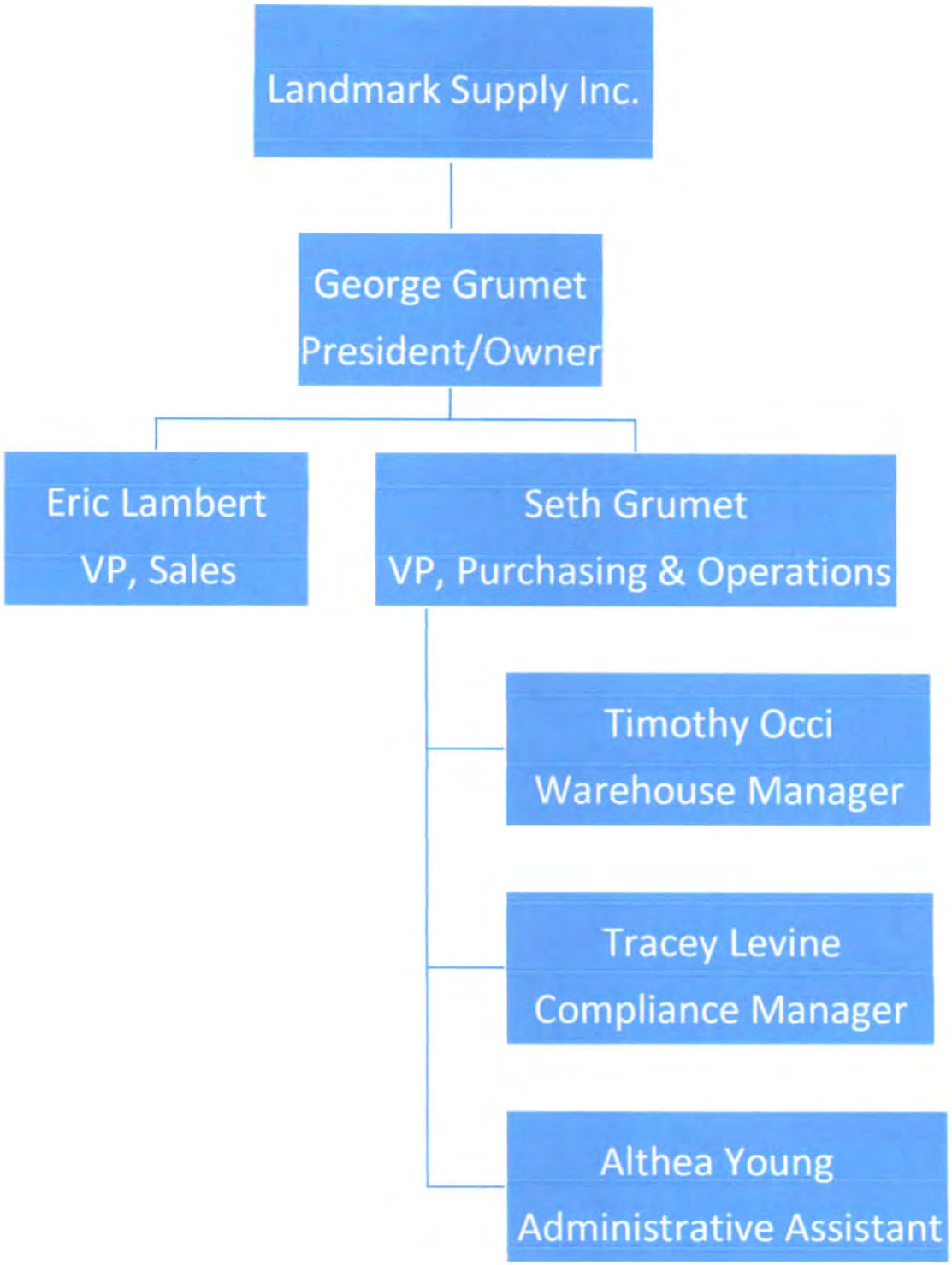
Address: 199 MAIN ST 2ND FL , KEANSBURG, NJ 07734

Original Issue Date: 09/08/2011 **Expiration Date:** 01/31/2022

Current Issue Date: 12/16/2020

Disciplines: No

Additional Registered Addresses:
440 RARITAN AVE, HIGHLAND PARK, NJ 08904


Landmark Supply Inc.
George Grumet
President/Owner
Eric Lambert
VP, Sales
Seth Grumet
VP, Purchasing & Operations
Timothy Occi
Warehouse Manager
Tracey Levine
Compliance Manager
Althea Young
Administrative Assistant

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through June 15, 2021

You have searched Finished drug products

Search Results: *'71862'*

Back to Search Page | Search Again

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Ibuprofen	71862-003-01	600 mg/1	TABLET	ORAL	ANDA202413	Landmark Supply Inc.	71862-003	Ibuprofen	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/01/2017	N/A	ANDA	100 TABLET in 1 BOTTLE (71862-003-01)	Cyclooxygenase Inhibitors [MoA], Anti-Inflammatory Agents, Non-Steroidal [CS], Nonsteroidal Anti-inflammatory Drug [EPC]
Ibuprofen	71862-007-01	800 mg/1	TABLET	ORAL	ANDA202413	Landmark Supply Inc.	71862-007	Ibuprofen	IBUPROFEN	HUMAN PRESCRIPTION DRUG	12/01/2017	N/A	ANDA	100 TABLET in 1 BOTTLE (71862-007-01)	Cyclooxygenase Inhibitors [MoA], Anti-Inflammatory Agents, Non-Steroidal [CS], Nonsteroidal Anti-inflammatory Drug [EPC]

Showing 1 to 2 of 2 entries

Previous 1 Next

verified
M.H 6/15/21

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Landmark Supply Inc

Physical Address 440 Raritan Avenue

City Highland Park State NJ Zip 08904

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 7327695008 Website www.landmarksupplyinc.com

Licensing Company Email landmarksupply@landmarksupplyinc.com

Section 2: Personal Information

First Eric Middle Michael Last Lambert

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

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

Mailing Address [redacted] Ocean Blvd

City Atlantic Highlands State NJ Zip 07716

Telephone [redacted] Email eric@landmarksupplyinc.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials EML

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

School Name		From - To (MM/YY – MM/YY)	
WEST VIRGINIA UNIVERSITY.		09/91 - 12/93	
Address	**City**	**State**	**Zip**
1500 UNIVERSITY AVENUE	MORGANTOWN	WV	26505.
Diploma/Degree obtained, if any			
BS. PHARM			

School Name		From - To (MM/YY – MM/YY)	
MARSHALL UNIVERSITY		06/85 - 06/90	
Address	**City**	**State**	**Zip**
1 JOHN MARSHALL DR.	HUNTINGTON	WV.	25755.
Diploma/Degree obtained, if any			
N/A.			

School Name		From - To (MM/YY – MM/YY)	
MILTON HIGH SCHOOL.		09/84 - 05/87	
Address	**City**	**State**	**Zip**
US RT 60 E	MILTON	WV.	25541
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/18 - PRESENT.	[redacted] OCEAN BLVD	ATLANTIC HIGHLANDS	NJ	07716
04/17 - 10/18	215 MCCLEES RD	RED BANK	NJ	07701
04/16 - 04/17	1 AMANDA CT.	ATLANTIC HIGHLANDS	NJ	07716
10/15 - 04/16	23 VILLAGE RD	SEA BRIGHT	NJ	07760
06/00 - 10/15	3537 BLUESULPHUR RD	ONA	WV.	25545.
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
Landmark Supply Inc		09/15 - Present
Business Address	**City**	**State / Zip**
440 Raritan Avenue	Highland Park	NJ 08904
Phone	**Title**	**Number of Employed Hours**
7327495008	VP, Purchasing	12,000

Description of Duties: SALES, OPERATIONS, POLICY & PROCEDURES, PURCHASING.

Business Name		From - To (MM/YY – MM/YY)
Holzer Family Pharmacy		4/13 - 09/15
Business Address	**City**	**State / Zip**
100 Jackson Pike	Gallipolis	OH 45631
Phone	**Title**	**Number of Employed Hours**
740-446-5236.	Pharmacist.	5,000.

Description of Duties: 340b oversight, filling Rx, immunizations, scheduling

Business Name		From - To (MM/YY – MM/YY)
Cabell Huntington Hospital		03/13 - 04/14.
Business Address	**City**	**State / Zip**
1340 Hal Greer Blvd	Huntington	WV. 25701.
Phone	**Title**	**Number of Employed Hours**
304-526-2000	Pharmacist	2,000

Description of Duties: Pharmacy operations, dispensing, work flow, 340b oversight.

Business Name		From - To (MM/YY – MM/YY)
Healthwarehouse.com.		01/11 - 01/12
Business Address	**City**	**State / Zip**
7107 Industrial Rd.	Florence	KY 41042.
Phone	**Title**	**Number of Employed Hours**
800-748-7001	VP of Pharmacy operations.	2,000.

Description of Duties: Purchasing, dispensing, warehouse operations, licensing, VIPPS oversight.

Business Name		From - To (MM/YY – MM/YY)
Rite Aid Pharmacy		02/12 - 03/13.
Business Address	**City**	**State / Zip**
3000 Teays Valley Rd.	Hurricane	WV. 25526
Phone	**Title**	**Number of Employed Hours**
304-562-1830	Pharmacist.	2,000

Description of Duties: Dispensing, scheduling, immunizations.

Continue on next page if additional space is needed.

Applicant's initials EML

Business Name		From - To (MM/YY – MM/YY)	
TRUST PHARMACY CORP. OFFICE.		12/99 - 01/11	
Business Address	**City**	**State**	**Zip**
4016 OHIO RIVER RD.	POINT PLEASANT	WV.	25550
Phone	**Title**	**Number of Employed Hours**	
304-675-1612	V.P. OF PHARMACY.	28,000.	

Description of Duties HIPAA officer, warehouse operations, scheduling, licensing, hiring, firing, pricing, software tech, prime vendor contracts, etc

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Applicant's initials Eml

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

Applicant's initials Erl.

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

N/A

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/20/21
Date

EM
Applicant's initials _____

I, ERIC M. LAMBERT, **certify that as the designated representative for** LANDMARK SUPPLY, INC.,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

ERIC LAMBERT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/26/21

Date

Applicant's initials EL

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

Eric Lambert

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/26/21

Date

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

State of NEW JERSEY, ss. County of SOMERSET

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

Original Signature

5/28/2021

Date

Subscribed and Sworn to before me this 28th day of MAY, 2021.

Notary Public Signature

NUNZIO GALLO

NOTARY PUBLIC OF NEW JERSEY

MY COMMISSION EXPIRES

SEPTEMBER 22,20 24

(Seal)

Applicant's initials EL

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Landmark Supply Inc.

Physical Address 440 Raritan Avenue

City Highland Park State NJ Zip 08904

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 7327695008 Website www.landmarksupplyinc.com

Licensing Company Email landmarksupply@landmarksupplyinc.com

Section 2: Personal Information

First George Middle _____ Last Glumet

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

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

Mailing Address [redacted] Phillips RD

City Edison State NJ Zip 08817

Telephone [redacted] Email [redacted]

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's Initials _____

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

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

School Name	LINDEN HIGH SCHOOL		From - To (MM/YY – MM/YY)	1956-1960
Address	ST. GEORGES AVE	**City** LINDEN	**State** NJ	**Zip** 07036
Diploma/Degree obtained, if any	HIGH SCHOOL DIPLOMA			

School Name	MARIETTA COLLEGE		From - To (MM/YY – MM/YY)	1960-1964
Address		**City** MARIETTA	**State** OHIO	**Zip**
Diploma/Degree obtained, if any	BACH. OF SCIENCE			

School Name	RUTGERS COLL. OF PHARMACY		From - To (MM/YY – MM/YY)	1964-1967
Address	NEW BRUNSWICK	**City** NEW BRUNSWICK	**State** NJ	**Zip** 08901
Diploma/Degree obtained, if any	PHARMACY DEGREE REGISTERED PHARMACIST 1968			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1973 – Present	[redacted] Phillips Rd	Edison	NJ	08817
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials DT

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

Business Name			From - To (MM/YY – MM/YY)	
Landmark Supply Inc			2012 - present	
Business Address		**City**	**State**	**Zip**
440 Raritan Avenue		Highland Park	NJ	08904
Phone	**Title**			
732-769-3008	owner			
Description of Duties				
owner of wholesale distributor of Prescription DRUGS				

Business Name			From - To (MM/YY – MM/YY)	
Keansburg DRUGS			2008 - 2014	
Business Address		**City**	**State**	**Zip**
199 Main Street 2nd Fl		Keansburg	NJ	07734
Phone	**Title**			
732-787-1414	owner			
Description of Duties				
owner - retail pharmacy				

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

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

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

Continue on next page if additional space is needed.

Applicant's initials JG

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

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

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

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

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

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

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

Applicant's initials _____

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/2/21

Date

Applicant's initials

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

GEORGE GRUMET

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/27/21

Date

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

State of NEW JERSEY, ss. County of MIDDLESEX

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

Original Signature

5/27/21

Date

Subscribed and Sworn to before me this 26th day of MAY 2021.

Notary Public Signature

NUNZIO GALLO

NOTARY PUBLIC OF NEW JERSEY

MY COMMISSION EXPIRES

SEPTEMBER 22,20 24

Sworn to and subscribed before me this 26th day of MAY 2021

(Seal)

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Landmark Supply Inc

Physical Address 440 Raritan Avenue

City Highland Park State NJ Zip 08904

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 7327695008 Website www.landmarksupplyinc.com

Licensing Company Email landmarksupply@landmarksupplyinc.com

Section 2: Personal Information

First SETH Middle Adam Last GRUMET

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

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

Mailing Address [redacted] Kings Court

City Marlboro State NJ Zip 07746

Telephone [redacted] Email [redacted]

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials _____

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

School Name			From - To (MM/YY – MM/YY)	
ROWAN UNIVERSITY			1988 - 1993	
Address		**City**	**State**	**Zip**
ROUTE 322		GLASSBORO	NJ	08028
Diploma/Degree obtained, if any				
BS				
School Name			**From - To (MM/YY – MM/YY)**	
RUTGERS PREP SCHOOL			1985 - 1988	
Address		**City**	**State**	**Zip**
EASTON AVE		SOMERSET	NJ	08873
Diploma/Degree obtained, if any				
HIGH SCHOOL DIPLOMA				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
3/03 - Present	[redacted] Kings Court	Marlboro	NJ	07746
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

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

Business Name			From - To (MM/YY – MM/YY)
Landmark Supply Inc.			9/12 - PRESENT
Business Address	**City**	**State**	**Zip**
440 Raritan AVENUE	Highland Park	NJ	08904
Phone	**Title**		
7327695008	VP, Purchasing - owner		
Description of Duties			
Wholesale distributor of prescription pharmaceuticals.			

Business Name			From - To (MM/YY – MM/YY)
Matrix Distributors			2-1-2000 - 08-2012
Business Address	**City**	**State**	**Zip**
110 Tices Lane	E. Brunswick	NJ	08816
Phone	**Title**		
732-698-9991	Owner		
Description of Duties			
Wholesale distributor of prescription pharmaceuticals.			

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

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

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

Continue on next page if additional space is needed.

Applicant's initials _____

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

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

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

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

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

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

Applicant's initials _____

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

Applicant's initials _____

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-27-21
Date

Applicant's initials _____

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

SETH GRUMET
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/25/21
Date

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

State of NEW JERSEY, ss. County of SOMERSET

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

Original Signature

5-25-21
Date

Subscribed and Sworn to before me this 28th day of MAY 2021.

Notary Public Signature

NUNZIO GALLO
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES
SEPTEMBER 22,2024

(Seal)

Applicant's initials _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. SU1163967

Application/License No. _____

Landmark Supply, Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 440 Raritan Avenue, Highland Park NJ 09804 (Address of Applicant/Principal), as PRINCIPAL, and Arch Insurance Company (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Harborside 3, 210 Hudson Street, Suite 300, Jersey City, NJ 07311 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 05/25/2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of June, 2021.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Melissa Propst

Surety Company's Representative

Melissa Propst, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

AIC 0000312056

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated. Not valid for Note, Loan, Letter of Credit, Currency Rate, Interest Rate or Residential Value Guarantees.

POWER OF ATTORNEY

Know All Persons By These Presents:
That the Arch Insurance Company, a corporation organized and existing under the laws of the State of Missouri, having its principal administrative office in Jersey City, New Jersey (hereinafter referred to as the "Company") does hereby appoint:

Benjamin Dycus, Kenneth Albert, LaKala Carter, Melissa Propst and Steven Baas of Bowling Green, KY (EACH)

its true and lawful Attorney(s)in-Fact, to make, execute, seal, and deliver from the date of issuance of this power for and on its behalf as surety, and as its act and deed: Any and all bonds, undertakings, recognizances and other surety obligations, in the penal sum not exceeding Ninety Million Dollars (90,000,000 00). This authority does not permit the same obligation to be split into two or more bonds In order to bring each such bond within the dollar limit of authority as set forth herein.

The execution of such bonds, undertakings, recognizances and other surety obligations in pursuance of these presents shall be as binding upon the said Company as fully and amply to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal administrative office in Jersey City, New Jersey.

This Power of Attorney is executed by authority of resolutions adopted by unanimous consent of the Board of Directors of the Company on September 15, 2011, true and accurate copies of which are hereinafter set forth and are hereby certified to by the undersigned Secretary as being in full force and effect:

"**VOTED**, That the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, or the Secretary shall have the power and authority to appoint agents and attorneys-in-fact, and to authorize them subject to the limitations set forth in their respective powers of attorney, to execute on behalf of the Company, and attach the seal of the Company thereto, bonds, undertakings, recognizances and other surety obligations obligatory in the nature thereof, and any such officers of the Company may appoint agents for acceptance of process."

This Power of Attorney is signed, sealed and certified by facsimile under and by authority of the following resolution adopted by the unanimous consent of the Board of Directors of the Company on September 15, 2011:

VOTED, That the signature of the Chairman of the Board, the President, or the Executive Vice President, or any Senior Vice President, of the Surety Business Division, or their appointees designated in writing and filed with the Secretary, and the signature of the Secretary, the seal of the Company, and certifications by the Secretary, may be affixed by facsimile on any power of attorney or bond executed pursuant to the resolution adopted by the Board of Directors on September 15, 2011, and any such power so executed, sealed and certified with respect to any bond or undertaking to which it is attached, shall continue to be valid and binding upon the Company. **In Testimony Whereof**, the Company has caused this instrument to be signed and its corporate seal to be affixed by their authorized officers, this **4th day of May, 2020**

Attested and Certified

Patrick K. Nails, Secretary

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

Arch Insurance Company

David M. Finkelstein, Executive Vice President

STATE OF PENNSYLVANIA SS
COUNTY OF PHILADELPHIA SS

I, **Michele Tripodi**, a Notary Public, do hereby certify that Patrick K. Nails and David M. Finkelstein personally known to me to be the same persons whose names are respectively as Secretary and Executive Vice President of the Arch Insurance Company, a Corporation organized and existing under the laws of the State of Missouri, subscribed to the foregoing instrument, appeared before me this day in person and severally acknowledged that they being thereunto duly authorized signed, sealed with the corporate seal and delivered the said instrument as the free and voluntary act of said corporation and as their own free and voluntary acts for the uses and purposes therein set forth

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
MICHELE TRIPODI, Notary Public
City of Philadelphia, Phila. County
My Commission Expires July 31, 2021

Michele Tripodi, Notary Public
My commission expires 07/31/2021

CERTIFICATION

I, **Patrick K. Nails**, Secretary of the Arch Insurance Company, do hereby certify that the attached **Power of Attorney dated May 4, 2020** on behalf of the person(s) as listed above is a true and correct copy and that the same has been in full force and effect since the date thereof and is in full force and effect on the date of this certificate; and I do further certify that the said David M. Finkelstein, who executed the Power of Attorney as Executive Vice President, was on the date of execution of the attached Power of Attorney the duly elected Executive Vice President of the Arch Insurance Company.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seal of the Arch Insurance Company on this 10th day of June 20 21.

Patrick K. Nails, Secretary

This Power of Attorney limits the acts of those named therein to the bonds and undertakings specifically named therein and they have no authority to bind the Company except in the manner and to the extent herein stated.

PLEASE SEND ALL CLAIM INQUIRIES RELATING TO THIS BOND TO THE FOLLOWING ADDRESS:
Arch Insurance – Surety Division
3 Parkway, Suite 1500
Philadelphia, PA 19102

Arch Insurance Company
CORPORATE SEAL 1971
Missouri

To verify the authenticity of this Power of Attorney, please contact Arch Insurance Company at SuretyAuthentic@archinsurance.com Please refer to the above named Attorney-in-Fact and the details of the bond to which the power is attached.

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

■ New Wholesaler or □ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

□ Publicly Traded Corporation – Pages 1,2,3,4
□ Partnership - Pages 1,2,3,7,8
■ Non Publicly Traded Corporation – Pages 1,2,3,5,6
□ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Nostrum Laboratories, Inc.

Physical Address: 1800 N Topping Ave

City: Kansas City State: MO Zip Code: 64120

Telephone Number: 816-841-4636 Fax Number: 816-308-4975

Toll Free Number: 314.973.9527

E-mail: jfoster@nostrumlabs.com Website: www.nostrumlabs.com

Facility Manager: John Foster

Professional qualifications and experience of facility manager: Bachelor of Science - Engineering

Types of licensed outlets or authorized persons firm will serve:

□ Pharmacies □ Practitioners □ Hospitals ■ Wholesalers
■ Other: Distributors

Type of Products to be handled or wholesaled by firm:

■ Legend Pharmaceuticals, Supplies or Devices
□ Poisons or Chemicals
■ Controlled Substances (include copy of DEA)
□ Other: _____
□ Hypodermic Devices
□ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ■
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ■ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ■

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Kaiser Permanente Foundation Hospital C/O UPS SUPPLY CHAIN SOLUTIONS INC
Address: 12055 SAGE POINT CT #101, Reno, NV 89506

Name: HENRY SCHEIN INC
Address: 255 Vista BLVD # 104, Sparks, NV 89434

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NA

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ■

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ■

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ■

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ■

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ■

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

John Foster

Original Signature of Person Authorized to Submit Application, no copies or stamps

John Foster

Print Name of Authorized Person

12.08.2020

Date

Board Use Only	Date Processed:_____	Amount: 600.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: NJ

Parent Company if any: Nostrum Pharmaceuticals, LLC

Mailing Address: 1370 Hamilton Street

City: Somerset State: NJ Zip: 08873

Telephone: 732-543-2440 Fax: 732-246-7215

Contact Person: Nirmal Mulye

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) 100% Owned by Nostrum Pharmaceuticals, LLC
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. NA

3) What was the price paid per share? NA

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NA

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Include with the application for a non-publicly traded corporation continued

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

***If you are a FDA registered manufacturer, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your FDA registration.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers only".

***If your company is **not** VAWD certified by NABP, or an FDA registered manufacturer you will need to complete the following:

- Submit fingerprints – Please refer to Fingerprint Submission Instructions

http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.

- Submit a list containing each employee(s) who handle the drugs on a daily basis.

- Copy of a bond in an amount of $100,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. Blank surety bond, certificate of deposit, letter of credit or cash deposit are included under the new application tab entitled "Wholesalers Only".

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

+

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **nostrum lab**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Nostrum Laboratories, Inc.	1518957	791055549	ANALYSIS; LABEL; MANUFACTURE; PACK;	705 East Mulberry Street, Bryan, Ohio (OH) 43506, United States (USA)	12/31/2021
Nostrum Laboratories, Inc.	1930436	791142354	ANALYSIS; LABEL; MANUFACTURE; PACK;	1800 N Topping Avenue, Kansas City, Missouri (MO) 64120, United States (USA)	12/31/2021

Showing 1 to 2 of 2 entries

Previous1Next

Data Current through: Wednesday, Dec 9, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified
12/22/2020
MS

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

NOSTRUM LABORATORIES INC.
0100970831

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on November 09, 2006.

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

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CTR
STE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 1st day of December, 2020

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6113369558

Verify this certificate online at

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

Corporate Officer Information

Nostrum Laboratories, Inc.

1800 N Topping Ave, Kansas City, MO 64120

FEIN: 20-5877688
Incorporated in the State of New Jersey on
11/09/2006

Parent Company	**Nostrum Pharmaceuticals LLC**
Address	1370 Hamilton Street Somerset NJ 08873
Ownership	100%

Nirmal Mulye	CEO
Carlton Asher	Secretary
Bernard Berk	President & Vice Chairman
John Foster	Vice President, Manufacturing & Engineering
Elaine Sims	Vice President, Quality

State of Missouri

Division of Professional Registration

Licensed Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2021

ORIGINAL CERTIFICATE/LICENSE NO. 2007002106

NOSTRUM LABORATORIES INC

NOSTRUM LABORATORIES INC

JOHN C. FOSTER, MIC

1800 NORTH TOPPING AVENUE

KANSAS CITY MO 64120

USA

NOSTRUM LABORATORIES INC
NOSTRUM LABORATORIES INC
JOHN C. FOSTER, MIC
1800 NORTH TOPPING AVENUE
KANSAS CITY MO 64120
USA

State of Missouri

Missouri Department of Commerce and Insurance

Division of Professional Registration

Missouri Board of Pharmacy

Licensed Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2021

ORIGINAL CERTIFICATE/LICENSE NO. 2007002106

John C Foster

NOSTRUM LABORATORIES INC

NOSTRUM LABORATORIES INC

JOHN C. FOSTER, MIC

1800 NORTH TOPPING AVENUE

KANSAS CITY MO 64120

USA

EXECUTIVE DIRECTOR

Sarah E. Edgerwood

DIVISION DIRECTOR

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nostrum Laboratories, Inc.

Physical Address: 1800 N Topping Ave

City: Kansas City State: MO Zip: 64120

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: Website:

Licensing Company Email: jfoster@nostrumlabs.com; backup email nayif.salah@iqvia.com

Section 2: Personal Information

First: John Middle: Clinton Last: Foster

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

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

Mailing Address: [redacted]North 123rd Street

City: Kansas City State: KS Zip: 66109

Telephone: [redacted] Email: jfoster@nostrumlabs.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials: JCF

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

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MISSOURI - ST LOUIS		08/98 - 05/04	
Address	City	State	**Zip**
1 UNIVERSITY BLVD.	ST. LOUIS	MO	63121
Diploma/Degree obtained, if any			
BS ENGINEERING-Major: CIVIL ENGINEERING Minor: STRUCTURAL			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF KANSAS		08/80 - 05/85	
Address	City	State	**Zip**
1450 JAYHAWK BLVD	LAWRENCE	KS	66045
Diploma/Degree obtained, if any			
BFA FINE ART-Major: FINE ART Minor: PAINTING			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - present	[redacted]N 123rd Street	Kansas City	KS	66109
04/19 - 08/20	117 W 20th Street	Kansas City	MO	64108
11/16 - 04/19	5000 N Marine Dr	Chicago	IL	60640
04/04 - 11/16	11 Oak Forest	Eureka	MO	63025

Applicant's initials JCF

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
NOSTRUM LABORATORIES INC			APRIL 2019 - CURRENT	
Business Address		City	State	Zip
1800 N Topping Ave		Kansas City	MO	64120
Phone	Title		Number of Employed Hours	
816-841-4636	VICE PRESIDENT OF MANUFACTURING/ENGINEERING		Fulltime	
Description of Duties				
Resume attached*				

Business Name			From - To (MM/YY – MM/YY)	
WOCKHARDT PHARMACEUTICAL			OCT 2018 - APR 2019	
Business Address		City	State	Zip
6451 Main Street		MORTON GROVES	IL	60053
Phone	Title		Number of Employed Hours	
847-967-5600	SENIOR DIRECTOR OF OPERATIONS		Fulltime	
Description of Duties				
Resume attached				

Business Name			From - To (MM/YY – MM/YY)	
WOCKHARDT PHARMACEUTICAL			OCT 2016 - DEC 2018	
Business Address		City	State	Zip
6451 Main Street		MORTON GROVES	IL	60053
Phone	Title		Number of Employed Hours	
847-967-5600	DIRECTOR OF ENGINEERING/MAINTENANCE/FACILITIE		Fulltime	
Description of Duties				
Resume attached				

Business Name			From - To (MM/YY – MM/YY)	
MALLINCKRODT PHARMACEUTICAL			MAR 2011 - AUG 2016	
Business Address		City	State	Zip
3501 N 2nd St		ST LOUIS	MO	63147
Phone	Title		Number of Employed Hours	
314-654-2000	ENGINEERING AND MAINTENANCE MANAGER		Fulltime	
Description of Duties				
Resume attached				

Business Name			From - To (MM/YY – MM/YY)	
MALLINCKRODT PHARMACEUTICAL			MAY 2009 - MAR 2011	
Business Address		City	State	Zip
100 Louis Latzer Dr		GREENVILLE	IL	62246
Phone	Title		Number of Employed Hours	
618-664-2111	ENGINEERING AND MAINTENANCE MANAGER		Fulltime	
Description of Duties				
Resume attached				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
KV PHARMACEUTICAL		08/06 - 05/09
Business Address	City	State / Zip
11756 Borman Dr	ST LOUIS	MO / 63146
Phone	Title	Number of Employed Hours
314-432-0800	CONSTRUCTION MANAGER	Fulltime
Description of Duties		
Resume attached		

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

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

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

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

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

JCF
Applicant's initials _____

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

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

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

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

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

Applicant's initials JCF

I, John Foster, **certify that as the designated representative for**

NOSTRUM LABORATORIES INC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

JCF

Applicant's initials

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

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

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

State of Missouri, ss. County of Jackson

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

Original Signature

06.16.2021

Date

Subscribed and Sworn to before me this 16th day of June 2021.

Andrea Tuso

Notary Public Signature

ANDREA TUSO
Notary Public - Notary Seal
State of Missouri
Commissioned for Jackson County
My Commission Expires: November 16, 2023
Commission Number: 11705157

(Seal)

JCF

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nostrum Laboratories, Inc.

Physical Address: 1800 N Topping Ave

City: Kansas City State: MO Zip: 64120

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: Website:

Licensing Company Email: jfoster@nostrumlabs.com; backup email nayif.salah@iqvia.com

Section 2: Personal Information

First: John Middle: Clinton Last: Foster

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

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

Mailing Address: 5033 North 123rd Street

City: Kansas City State: KS Zip: 66109

Telephone: [redacted] Email: jfoster@nostrumlabs.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials: JCF

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

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MISSOURI - ST LOUIS		08/98 - 05/04	
Address	**City**	**State**	**Zip**
1 UNIVERSITY BLVD.	ST. LOUIS	MO	63121
Diploma/Degree obtained, if any			
BS ENGINEERING-Major: CIVIL ENGINEERING Minor: STRUCTURAL			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF KANSAS		08/80 - 05/85	
Address	City	State	Zip
1450 JAYHAWK BLVD	LAWRENCE	KS	66045
Diploma/Degree obtained, if any			
BFA FINE ART-Major: FINE ART Minor: PAINTING			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - present	[redacted]N 123rd Street	Kansas City	KS	66109
04/19 - 08/20	117 W 20th Street	Kansas City	MO	64108
11/16 - 04/19	5000 N Marine Dr	Chicago	IL	60640
04/04 - 11/16	11 Oak Forest	Eureka	MO	63025

Applicant's initials JCF

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
NOSTRUM LABORATORIES INC			APRIL 2019 - CURRENT
Business Address	**City**	**State**	**Zip**
1800 N Topping Ave	Kansas City	MO	64120
Phone	**Title**		**Number of Employed Hours**
816-841-4636	VICE PRESIDENT OF MANUFACTURING/ENGINEERING		Fulltime
Description of Duties			
Resume attached*			

Business Name			From - To (MM/YY – MM/YY)
WOCKHARDT PHARMACEUTICAL			OCT 2018 - APR 2019
Business Address	**City**	**State**	**Zip**
6451 Main Street	MORTON GROVES	IL	60053
Phone	**Title**		**Number of Employed Hours**
847-967-5600	SENIOR DIRECTOR OF OPERATIONS		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
WOCKHARDT PHARMACEUTICAL			OCT 2016 - DEC 2018
Business Address	**City**	**State**	**Zip**
6451 Main Street	MORTON GROVES	IL	60053
Phone	**Title**		**Number of Employed Hours**
847-967-5600	DIRECTOR OF ENGINEERING/MAINTENANCE/FACILITIE		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
MALLINCKRODT PHARMACEUTICAL			MAR 2011 - AUG 2016
Business Address	**City**	**State**	**Zip**
3501 N 2nd St	ST LOUIS	MO	63147
Phone	**Title**		**Number of Employed Hours**
314-654-2000	ENGINEERING AND MAINTENANCE MANAGER		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
MALLINCKRODT PHARMACEUTICAL			MAY 2009 - MAR 2011
Business Address	City	State	Zip
100 Louis Latzer Dr	GREENVILLE	IL	62246
Phone	Title		Number of Employed Hours
618-664-2111	ENGINEERING AND MAINTENANCE MANAGER		Fulltime
Description of Duties			
Resume attached			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)
KV PHARMACEUTICAL		08/06 - 05/09
Business Address	City	State / Zip
11756 Borman Dr	ST LOUIS	MO / 63146
Phone	Title	Number of Employed Hours
314-432-0800	CONSTRUCTION MANAGER	Fulltime
Description of Duties		
Resume attached		

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

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

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

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

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

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

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

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

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

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

06.15.2021
Date

Applicant's initials JCF

I, John Foster, **certify that as the designated representative for**

NOSTRUM LABORATORIES INC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

Applicant's initials JCF

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

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

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

State of Missouri, ss. County of Jackson

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

Original Signature

06.16.2021

Date

Subscribed and Sworn to before me this 16th day of June 2021.

Notary Public Signature

ANDREA TUSO
Notary Public - Notary Seal
State of Missouri
Commissioned for Jackson County
My Commission Expires: November 16, 2023
Commission Number: 11705157

(Seal)

Applicant's initials JCF

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nostrum Laboratories, Inc.

Physical Address: 1800 N Topping Ave

City: Kansas City State: MO Zip: 64120

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: Website:

Licensing Company Email: jfoster@nostrumlabs.com; backup email nayif.salah@iqvia.com

Section 2: Personal Information

First: John Middle: Clinton Last: Foster

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

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

Mailing Address: [redacted] North 123rd Street

City: Kansas City State: KS Zip: 66109

Telephone: [redacted] Email: jfoster@nostrumlabs.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials: JCF

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

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MISSOURI - ST LOUIS		08/98 - 05/04	
Address	**City**	**State**	**Zip**
1 UNIVERSITY BLVD.	ST. LOUIS	MO	63121
Diploma/Degree obtained, if any			
BS ENGINEERING-Major: CIVIL ENGINEERING Minor: STRUCTURAL			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF KANSAS		08/80 - 05/85	
Address	City	State	Zip
1450 JAYHAWK BLVD	LAWRENCE	KS	66045
Diploma/Degree obtained, if any			
BFA FINE ART-Major: FINE ART Minor: PAINTING			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - present	[redacted] N 123rd Street	Kansas City	KS	66109
04/19 - 08/20	117 W 20th Street	Kansas City	MO	64108
11/16 - 04/19	5000 N Marine Dr	Chicago	IL	60640
04/04 - 11/16	11 Oak Forest	Eureka	MO	63025
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
NOSTRUM LABORATORIES INC			APRIL 2019 - CURRENT
Business Address	**City**	**State**	**Zip**
1800 N Topping Ave	Kansas City	MO	64120
Phone	**Title**		**Number of Employed Hours**
816-841-4636	VICE PRESIDENT OF MANUFACTURING/ENGINEERING		Fulltime
Description of Duties			
Resume attached*			

Business Name			From - To (MM/YY – MM/YY)
WOCKHARDT PHARMACEUTICAL			OCT 2018 - APR 2019
Business Address	**City**	**State**	**Zip**
6451 Main Street	MORTON GROVES	IL	60053
Phone	**Title**		**Number of Employed Hours**
847-967-5600	SENIOR DIRECTOR OF OPERATIONS		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
WOCKHARDT PHARMACEUTICAL			OCT 2016 - DEC 2018
Business Address	**City**	**State**	**Zip**
6451 Main Street	MORTON GROVES	IL	60053
Phone	**Title**		**Number of Employed Hours**
847-967-5600	DIRECTOR OF ENGINEERING/MAINTENANCE/FACILITIE		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
MALLINCKRODT PHARMACEUTICAL			MAR 2011 - AUG 2016
Business Address	**City**	**State**	**Zip**
3501 N 2nd St	ST LOUIS	MO	63147
Phone	**Title**		**Number of Employed Hours**
314-654-2000	ENGINEERING AND MAINTENANCE MANAGER		Fulltime
Description of Duties			
Resume attached			

Business Name			From - To (MM/YY – MM/YY)
MALLINCKRODT PHARMACEUTICAL			MAY 2009 - MAR 2011
Business Address	City	State	Zip
100 Louis Latzer Dr	GREENVILLE	IL	62246
Phone	Title		Number of Employed Hours
618-664-2111	ENGINEERING AND MAINTENANCE MANAGER		Fulltime
Description of Duties			
Resume attached			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
KV PHARMACEUTICAL			08/06 - 05/09	
Business Address		City	State	Zip
11756 Borman Dr		ST LOUIS	MO	63146
Phone	Title		Number of Employed Hours	
314-432-0800	CONSTRUCTION MANAGER		Fulltime	
Description of Duties				
Resume attached				

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

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

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

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

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

Applicant's initials JCF

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

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

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

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

Provide explanation below:

NA

Original Signature (electronic, copies or stamps not accepted)

06.15.2021
Date

Applicant's initials JCF

I, John Foster, **certify that as the designated representative for** NOSTRUM LABORATORIES INC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

Applicant's initials JCF

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

John Foster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06.15.2021

Date

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

State of Missouri, ss. County of Jackson

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

Original Signature

06.16.2021

Date

Subscribed and Sworn to before me this 16th day of June 2021.

Notary Public Signature

ANDREA TUSO
Notary Public - Notary Seal
State of Missouri
Commissioned for Jackson County
My Commission Expires: November 16, 2023
Commission Number: 11705157

(Seal)

Applicant's initials JCF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107231260

Application/License No. _____

Nostrum Laboratories, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1800 N. Topping Ave., Kansas City, MO 64120, as
(Address of Applicant/Principal)
PRINCIPAL, and Travelers Casualty and Surety Company of America, a
(Surety Company)
corporation organized under the laws of the state of CT
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Tower Square , Hartford, CT 06183 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on December 1, 2020.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of December, 2020.

APPLICANT/PRINCIPAL

Nostrum Laboratories, Inc.

By: _____
Authorized Representative

SURETY COMPANY

Travelers Casualty and Surety Company of Am

By: Barbara Talty
Surety Company's Representative

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA HARTFORD, CONN.

Barbara Talty, Attorney-in-fact
print name

Surety Phone No. 860-277-0111

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

Countersigned by:

_____
Non-Nevada Resident Agent

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Barbara Talty of **Kansas City, MO**, their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law, including the following bond:

Surety Bond No.: 107231260
OR
Project Description: Pharmaceutical Wholesaler Surety Bond

Principal: Nostrum Laboratories, Inc.
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **6th** day of **May, 2019.**

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **6th** day of **May, 2019**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificetes of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificete relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 1st day of December, 2020.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which this Power of Attorney is attached.

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: TECHLAB, Inc.

Physical Address: 20 Corporate Drive

City: Radford State: VA Zip Code: 24141

Telephone Number: 540-953-1664 Fax Number: 540-953-1665

Toll Free Number: N/A

E-mail: statelicensing@techlab.com Website: www.techlab.com

Facility Manager: Steven E Harvey

Professional qualifications and experience of facility manager: 25.5 Years of experience in the medical devices industry and an educational background that includes a BS in Biology and Chemistry.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Robert Day

Print Name of Authorized Person

3/11/2021

Date

Board Use Only Date Processed:_____ Amount: 500 check # 056043

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Virginia

Parent Company if any: TechLab Holding Co

Mailing Address: 2001 Kraft Drive

City: Blacksburg State: VA Zip: 24060

Telephone: 540-953-1664 Fax: 540-953-1664

Contact Person: Robert Day

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Virginia Department of Health Professions
License Lookup

Current as of 05/21/2021 11:59

License Information

License Number	0216000187
Occupation	Warehouser
Name	TECHLAB, Inc
Address	Robert M. Day 20 Corporate Drive Radford, VA 24141
Initial License Date	02/08/2021
Expire Date	02/28/2022
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* *"Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

LISTING OF SECURITY FEATURES ON REVERSE SIDE

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

BOARD OF PHARMACY

Warehouser Permit

TECHLAB, Inc

Robert M. Day
20 Corporate Drive
Radford VA 24141

Number
0216000187

To verify the status of this permit, visit our website www.dhp.virginia.gov, which is a primary source verification of the credential issued by the Commonwealth of Virginia. To File a Complaint About a Licensee, Call: 1-800-533-1560.

36 D400IP1 24141

Security Features	Fraud Indicator:
Security Tint background	- The word "COPY" appearing on document.
Colored background	- Absence of color or pattern on face of license
Microprinting	- Micro-printed text appears as a solid or jagged line when copied and is not readable under magnification.
Security Box	- The word "ORIGINAL DOCUMENT" in white in a light screen tint box on back. When copied the screen tint disappears, therefore, the "ORIGINAL DOCUMENT" verbiage no longer appears.
Warning Verbiage	- Alerts handler that the document contains security features.

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That TECHLAB, INC. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on September 19, 1989;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

February 14, 2021

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2021021415496144

TECHLAB®

PROVEN PERFORMANCE IN
GI DISEASE DIAGNOSTICS

List of Officers

Daniel Delaney
Chief Executive Officer
DOB: [redacted]
SSN: [redacted]
Address: [redacted] Linwood Circle, Princeton, NJ 08540
Phone: [redacted]
Email: ddelaney@techlab.com

Robert Day
Chief Operating Officer
DOB: [redacted]
SSN: [redacted]
Address: [redacted] Manor Street, Roanoke, VA 24019
Phone: [redacted]
Email: rday@techlab.com

Kelly Bewick
Chief Financial Officer
DOB: [redacted]
SSN: [redacted]
Address: [redacted] Wakefield Drive Blacksburg, VA 24060
Phone: [redacted]
Email: kbewick@techlab.com

Steven E. Harvey

[redacted] Madison St.
Radford, VA 24141
[redacted]
sharvey@techlab.com

Experience

TechLab Inc, Blacksburg, Virginia., June 1995 - present

Vice President of Manufacturing and Radford Operations October 2015 to present

Oversee and direct TechLab's Radford Manufacturing and Distribution facility including Biological Materials Production, Manufacturing, Inventory Management, Operations, Distribution and Warehousing, and companywide Equipment Maintenance and Facility Maintenance.

Director of Manufacturing June 2014 - October 2015

New Facility Project Manager

- Assisted in design of 34,000 square foot manufacturing, distribution, and research and development facility, 2005
- Designed and supervised construction of 60,000 square foot manufacturing and distribution facility, 2011 – 2012
- Directing subcontractors and maintenance for two business locations
- Supervise maintenance and repair of automated equipment

Production Manager, October 1995 - June 2014

Directs a staff of 35

- Hire and train production staff
- Conduct annual performance reviews

- Represents department on multiple committees within the company, including design control and validation.
- Maintain GMP production and distribution facility for Class I and II medical devices
  - Manufacture ELISA and Lateral Flow Test kits
  - Write standard operating procedures and device master batch records
- Capital equipment responsibilities
  - Research and order new equipment
  - Develop and implement validation protocols
  - Plan scheduled maintenance and revalidations
- Business management
  - Budget capital equipment and personnel
    - Integrate company business strategy into monthly or yearly budgets
  - Forecast

        - Analyze historical sales, marketing, pricing, and demographic data to create an accurate and reliable financial forecast
    - Schedule
        - Initiate vendor shipments
        - Plan daily and monthly production schedule
        - Lead daily department meetings
- Assist product development
    - Evaluate raw materials
    - Test and implement methods
    - Work with Research and Development to formulate reagents
- Miscellaneous
    - On-call 24/7 for refrigerator, mechanical, and alarm needs
    - A licensed forklift operator

Board Member for New River Community College, 2013 - Present
Appointed by Radford City
Chairman of the Board July 2016 to Present

Board Member for New River Community College district for Manufacturing Technology Center for South West Virginia June 2013 - Present
Appointed in June 2013

Board Member for Radford City Economic Development June 2016 - Present
Vice-Chairman

Quality Auditor, 2003 - 2005
- Perform interdepartmental quality audits
- Responsible for production facility attaining ISO 9001:2000 and ISO 13485:1996 certification

Safety Manager, 1998 - 2005
- Maintained OSHA requirements
- Trained new employees in Chemical Hygiene, Blood Born Pathogens, and Forklift Safety
- Passed many external safety audits required for National Institutes of Health, Bio-safety Level II grant funding and OSHA inspection

Network Administrator, 1997 - 2008
- Assist in maintenance of 30 workstations and 2 servers
- Provide technical support for 50 users
- Install and upgrade software

Research and Development Technician, June 1995 - October 1995
- Performed optimization of diagnostic test kit before clinical trials

Education

- Bachelor of Science, May 1995, Radford University, Radford, Virginia
  Major: Biology and Chemistry
  Minor: Mathematics

Continuing Education:

- Manufacturing Lateral Flow Devices BBI Diagnostics
- Microbial Monitoring
- Operations Management
- Mastering Microsoft Access
- Upgrading and Maintaining PC's
- Fundamentals of Validations
- Lean Six Sigma Green Belt, obtained from NRCC, April 2011

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
TECHLAB INC.
20 Corporate Drive
Radford , VA 24141
Registration Number: 3009935129
FEI Number*: 3009935129
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
TECHLAB INC., CORPORATE RESEARCH CENTER
2001 KRAFT DR.
Blacksburg, VA US 24060
Owner/Operator Number: 9001581

Official Correspondent:
Donna T Link
2001 KRAFT DR.
Blacksburg, VA 24060
Phone: 540-9531664

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified M.H 5/04/2021

Page Last Updated: 05/17/2021
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

From: Donna Link
To: Carlyn Ruble
Cc: Kimberly Bulls
Subject: FW: Registration Number 3009935129: Successful 2021 Medical Device Establishment Registration
Date: Monday, February 22, 2021 5:53:54 PM
Attachments: SignatureBlockLogo.png

Donna Link
Director Regulatory & Compliance, Technical Services

2001 Kraft Drive
Blacksburg, VA 24060
Main: 800.832.4522
Mobile: 540.808.7584
Fax: 540953.1665
www.techlab.com

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Friday, December 11, 2020 7:58 PM
To: Donna Link <dlink@techlab.com>
Subject: Registration Number 3009935129: Successful 2021 Medical Device Establishment Registration

Dear DONNA LINK:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2021:

Registration Number: 3009935129
Owner Operator Number: 9001581
TECHLAB INC.
20 Corporate Drive
Radford, VA 24141
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a

duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2021. Registration for 2022 will be conducted between October 1 and December 31, 2021.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Imports & Registration and Listing Team
Division 2 Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1
Email: reglist@cdrh.fda.gov



GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: License & Permit

Bond No. : 60138724

Dated effective: 5/4/2021
(MONTH, DAY, YEAR)

executed by: TechLab, Inc., **as Principal,**
(PRINCIPAL)

and by: Capitol Indemnity Corporation, **as Surety,**
(SURETY)

and in favor of : Nevada State Board of Pharmacy.
(OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	2001 Kraft Dr.	20 Corporate Drive
Principal City	Blacksburg	Radford
Principal Zip	24060	24141

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 5/4/2021
(MONTH, DAY, YEAR)

Signed and Sealed 5/25/2021
(MONTH, DAY, YEAR)

Capitol Indemnity Corporation
SURETY

BY: _____
Lauren Blair, ATTORNEY-IN-FACT

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

60138726

KNOW ALL MEN BY THESE PRESENTS, That the **CAPITOL INDEMNITY CORPORATION**, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------KEVIN MCDANIEL; ANNE M. GLIEDT; STEPHANIE L. KLEARMAN; DEANNA M. MAURER; LISA A. MCALLEENAN----------
----------MARK R. DUGGAN; SCOTT P. REILLY; LAUREN BLAIR----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

---------- ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice presidents, assistant secretaries and attorneys(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner - Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 3rd day of May, 2017.

Attest:

John E. Rzepinski
Vice President, Treasurer & CFO

Suzanne M. Broadbent
Assistant Secretary

SEAL

CAPITOL INDEMNITY CORPORATION

Stephen J. Sills
CEO & President

STATE OF WISCONSIN } S.S.
COUNTY OF DANE }

On the 3rd day of May, 2017 before me personally came Stephen J. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN } S.S.
COUNTY OF DANE }

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 25th day of May 20 21

SEAL

Antonio Celii
General Counsel, Vice President & Secretary

THIS DOCUMENT IS NOT VALID UNLESS PRINTED ON GRAY SHADED BACKGROUND WITH A RED SERIAL NUMBER IN THE UPPER RIGHT HAND CORNER. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450. CIC-POA (Rev. 10-2017)

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 60138724

Application/License No. _____

TechLab, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2001 Kraft Dr., Blacksburg, VA 24060 (Address of Applicant/Principal), as PRINCIPAL, and Capitol Indemnity Corporation (Surety Company), a corporation organized under the laws of the state of WI (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 500 West Monroe, Suite 3500 , Chicago, IL 60661 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 4, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of May, 2021.

APPLICANT/PRINCIPAL
TechLab, Inc.

By: Kelly Brinch
Authorized Representative

SURETY COMPANY
Capitol Indemnity Corporation

By: Lauren Blair
Surety Company's Representative

Lauren Blair, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

White
Witness

Witness

SIGNED and SEALED in the presence of:

Debra Kohlman
Witness

Witness

Countersigned by:
N/A
Nevada Resident Agent

CAPITOL INDEMNITY CORPORATION
POWER OF ATTORNEY

60138724

KNOW ALL MEN BY THESE PRESENTS, That the CAPITOL INDEMNITY CORPORATION, a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------KEVIN MCDANIEL; ANNE M. GLIEDT; STEPHANIE L. KLEARMAN; DEANNA M. MAURER; LISA A. MCALLEENAN----------
----------MARK R. DUGGAN; SCOTT P. REILLY; LAUREN BLAIR----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all Bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

---------- ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of CAPITOL INDEMNITY CORPORATION at a meeting duly called and held on the 8th day of January, 2002.

"RESOLVED, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the CAPITOL INDEMNITY CORPORATION has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 3rd day of May, 2017.

Attest:

John E. Rzepinski
Vice President, Treasurer & CFO

Suzanne M. Broadbent
Assistant Secretary

SEAL

CAPITOL INDEMNITY CORPORATION

Stephen J. Sills
CEO & President

STATE OF WISCONSIN }
COUNTY OF DANE } S.S.

On the 3rd day of May, 2017 before me personally came Stephen J. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is President of CAPITOL INDEMNITY CORPORATION, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN }
COUNTY OF DANE } S.S.

I, the undersigned, duly elected to the office stated below, now the incumbent in CAPITOL INDEMNITY CORPORATION, a Wisconsin Corporation authorized to make this certificate, DO HEREBY CERTIFY that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 4th day of May, 20 21

SEAL

Antonio Celi
General Counsel, Vice President & Secretary

THIS DOCUMENT IS NOT VALID UNLESS PRINTED ON GRAY SHADED BACKGROUND WITH A RED SERIAL NUMBER IN THE UPPER RIGHT HAND CORNER. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450. CIC BOARRes 10-2017

CAREFULLY DETACH CARD HERE
↘

COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

Warehouser
Number 0216000187
TECHLAB, Inc

To verify the current status of any license, permit or registration, visit our website at www.dhp.virginia.gov.

Any name or address change requires the submission of a new application. Please visit our website at www.dhp.virginia.gov/pharmacy.

FOLD, CREASE AND TEAR ALONG PERFORATION

Renewal instructions will be furnished via email approximately 60 days in advance of expiration. Please refer to the Regulations for standards of practice.

To verify the current status and expiration date of this permit, visit our website at www.dhp.virginia.gov.

PLEASE NOTE: This copy of your permit contains no expiration date and should be maintained, carried, or posted, in accordance with applicable laws and regulations, for the duration of your practice. You will not receive another paper permit at your next renewal.

LISTING OF SECURITY FEATURES ON REVERSE SIDE

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

David E. Brown, D.C., Director

Caroline D. Juran
Executive Director
(804) 367-4456

BOARD OF PHARMACY

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
www.dhp.virginia.gov/pharmacy

Warehouser Permit

TECHLAB, Inc

2001 Kraft Drive
Blacksburg VA 24060

Number
0216000187

To verify the status of this permit, visit our website www.dhp.virginia.gov, which is a primary source verification of the credential issued by the Commonwealth of Virginia. To File a Complaint About a Licensee, Call: 1-800-533-1560.

Virginia Department of Health Professions
License Lookup

Current as of 02/12/2021 16:11

License Information

License Number	0216000187
Occupation	Warehouser
Name	TECHLAB, Inc
Address	2001 Kraft Drive Blacksburg, VA 24060
Initial License Date	02/08/2021
Expire Date	02/28/2022
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

** "Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Owens & Minor Distribution, Inc.

Physical Address: 5125 Ontario Mills Parkway

City: Ontario State: CA Zip Code: 91764

Telephone Number: (909) 944-2100 Fax Number: (909) 944-2198

Toll Free Number: (800) 488-8850

E-mail: OWM@slsny.com Website: www.owens-minor.com

Facility Manager: Gerardo Castellanos

Professional qualifications and experience of facility manager: Manages facility space exceeding 500,000 square feet. Leads 24 employees of the facility, ensuring its efficient operation.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Distribution sites with organization; US Government

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Hypodermic Devices
☐ Poisons or Chemicals
☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: Devices (Delivered to Patients, non-respiratory), Devices (OTC); Drugs (OTC)

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☒ No ☐
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Cardinal Health Medical
Address: 1450 Waukegan Road, Deerfield, IL 60015-220

Name: Becton Dickinson
Address: 1 Becton Drive, Franklin Lakes, NJ 07417-181

Name: ICU Medical
Address: 8401 West 102nd St Suite 300 Dept. 099D Bldg. HW2, Pleasant Prairie, WI 53158

Name: Medline Industries
Address: 1 Medline Place, Mundelein, IL 60060-448

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Michael W. Lowry
Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael W. Lowry — 3/9/21
Print Name of Authorized Person — Date

Board Use Only	Date Processed: 6/30/2021	Amount: 500 Check #3774

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: VA

Parent Company if any: Owens & Minor Distribution, Inc.

Mailing Address: Owens & Minor Distribution, Inc. c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Fax: (845) 544-2481

Contact Person: Jennifer Schneider

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

Owens & Minor Distribution, Inc. is the sole owner - no other owners to disclose.

a) Owens & Minor Distribution, Inc. (Name) 9120 Lockwood Blvd., Mechanicsville, VA 23116 (Business Address)

b) _____ (Name) _____ (Business Address)

c) _____ (Name) _____ (Business Address)

d) _____ (Name) _____ (Business Address)

2) Provide the number of shares issued by the corporation. N/A- Owens & Minor is the 100 percent sole owner

3) What was the price paid per share? N/A- Owens & Minor is the 100 percent sole owner

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Homestate License

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

LICENSE NO. WLS 6497
RECEIPT NO. 00170102

VALID UNTIL JANUARY 01, 2022

OWENS & MINOR DISTRIBUTION INC
5125 ONTARIO MILLS PARKWAY
ONTARIO CA 91764

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

11/19/20
11/19/20 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

March 17, 2021

State Licensing Servicing, Inc.
1751 State Route 17A, Suite 3
Florida, NY 19021

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: OWENS & MINOR DISTRIBUTION INC

License Type: WHOLESALER

License Number: WLS 6497

Status: ACTIVE

Issue Date: 01/05/2015

Expiration Date: 01/01/2022

Address of Record: 5125 ONTARIO MILLS PARKWAY ONTARIO CA 91764

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Barbera Schleicher
Individual Licensing Resource Analyst
(916) 518-3033
Barbera.Schleicher@dca.ca.gov

Good Standing

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That OWENS & MINOR DISTRIBUTION, INC. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on August 22, 2001;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

January 4, 2021

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2021010415310000

Owens & Minor Distribution, Inc.

Corporate Address: 9120 Lockwood Blvd., Mechanicsville, VA 23116 USA
FEIN: 54-2049200
www.owens-minor.com

Drug Labeler Code: N/A
Incorporation State: VA
Incorporation Date: 8/22/2001

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
CGO	437 Tower Blvd. Carol Stream, IL 60188 County: Dupage	N/A	N/A	00-794-1230	Yes	(630) 588-2800	(630) 588-2801

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License	
Nicholas Joseph Pace II	5 Kanawha Road Richmond, VA 23226	President, CEO & Corporate Secretary	No	[redacted]			*DR for LA-DME only*
Ryan Andrew Pohlman	601 Grace Dr. Lake In The Hills, IL 60156	Warehouse Lead	No	[redacted]			*Primary DR - DR for CA Wholesaler*

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Owens & Minor, Inc.	9120 Lockwood Blvd. Mechanicsville, VA 23116	N/A	100	N/A	54-1701843	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License	
Nicholas Joseph Pace II	5 Kanawha Road Richmond, VA 23226	President, CEO & Corporate Secretary	No	[redacted]			*DR for LA-DME only*
Michael W. Lowry	7488 Quail Run Lane Mechanicsville, VA 23116	SVP, Chief Financial Officer	No	[redacted]			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corporation			

Disciplinary History: LA 2002, CA 2006, FL 2007, MO 2008, CO 2009, FL 2010, LA 2011, VT 2011, CO 2012, HI 2013, CA 2013, KY 2014, VT 2015, AL 2016, HI 2016, WI 2016, CO 2017, HI 2017, CO 2018, FL 2019, CO 2020, CO 2019

DR Resume

GERARDO CASTELLANOS

Operations Supervisor

[redacted] Trinity Loop.
Ontario, CA 91764
[redacted]

Skills

- **CORE COMPETENCIES:** Distribution, Warehouse Management, Inventory/Stock Control, P&L, Leadership and Collaboration, Maintenance, Improving Process, Compliance and Safety, Customer/Client Service
  TECHNICAL SKILLS: Microsoft Office (Word, Excel, PowerPoint); Warehouse Management Systems, Synapse, AS400, MFG Pro, RF Links, CSW, OMNI, RedPrairie
- **LANGUAGES**: English (Fluent); Spanish (Native)
- **OTHER SKILLS**: Analytical, Adaptable, Excellent written and verbal communication skills, Creative problem-solving, Detail-oriented, Numeracy skills

Certifications & Training

EMT Certification, 2016, and 2019

Forklift Safety Instructor Certified (Crown), 2013, 2016, and 2019

Education

DEGREE
Mt Sac, Pomona, CA
2016 – 2022 (Expected)

H.S DIPLOMA
Ganesha High School, Pomona, CA

Qualifications Summary

- Focused Distribution Management Specialist with 20+ years of experience in distribution, inventory, overall transportation scheduling, inbound receiving and storage, returns and outbound pick and pack operations, and shipping for the healthcare, transportation and logistics industries. Building and Maintenance Manager for 15+ years; oversees the installation, repair, and maintenance of buildings and property; complied to company and industry safety standards.
- Communicated control deficiencies, resolved customer issues, logistics, and product issues; identified gaps to improve operations. Collaborates with contractors and service providers.
- Over three years of full-time experience in the pharmaceutical industry in a capacity of handling, shipping, dispensing and distribution of specialized drugs.

Work Experience

Operations Supervisor | Owens & Minor City of Industry, Redlands, and Ontario, CA SEP 2006 – PRESENT

Manages facility space exceeding 500,000 square feet. Leads 24 employees of the facility, ensuring its effective operation by preparing work schedules, assigning tasks, coordinating the flow of work and assigned projects, overseeing completion of work, and monitoring performance of the team for a global healthcare solutions company.

- **Compliance & Safety**: Ensured regulatory compliance with State Board of Pharmacy, FDA, DEA and any other local government agencies. Committed to accuracy, fill rates, delivery expectations, contract compliance, invoice match rates and agreed upon service matrix expectations.
- **Customer/Client Service:** Provides consistent, high level of service to major hospital, physician, and surgery center markets. Assists in customer service department functions.
- **Distribution/Warehouse Management/P&L**: Manages the daily facility operations including shipping and receiving, financial planning with P&L review responsibilities, staffing, transportation, budgeting, contracts, accounts receivables and payables, purchasing, human resource decisions, and capital requests.

Accomplishments:

- Leads the Surgitrack team and deployment to four accounts.
- As Crown Certified Trainer for the onboarding new MHE operators.
- Designated Representative License held for 11+ years.

WAREHOUSE SUPERVISOR |Weber Distribution 3PL, Fontana, Ca |SEP 2005 – SEP 2006

Efficiently managed day-to-day operation with focus on managing warehouse associates and implementing warehouse action plans for a company providing logistical services.

- **Leadership & Collaboration:** Trained and developed new employees and management level personnel. Attended Senior Management meetings; recommended ways to boost productivity.
- **Improving Process**: Analyzed current customers supply chain in order to reduce cost. Managed an efficient logistics operation by developing best in class processes.
- **Distribution/Warehouse Management/P&L**: Supervised receiving, order processing, inventory control, and shipping departments to ensure a smooth operation workflow.

Earlier Positions Held

WAREHOUSE SUPERVISOR
Pacific Coast Warehouse 3PL, Chino, CA|JUN 2004 - SEP 2005
National Distribution Center 3PL, Corona, CA | MAY 2002 - JUN 2004

- Led 20-28 associates; managed all functions of warehousing (structures from 294,000 sq. ft. - 309,000 sq. ft.)
- Increased productivity 20% through changes in operations and improved warehouse layout.
- Successful startup of the new facility - National Distribution Center 3PL.
- Conducted forklift certification classes and weekly safety meetings for 25-50 personnel.

855



The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®
Accreditation

to

Owens & Minor Distribution, Inc

located at

5125 Ontario Mills Parkway, Ontario, CA 91764

This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.

Carmen A. Catizone, Executive Director/Secretary

July 15, 2018 - July 14, 2021
Period of Accreditation

Verified
4/5/21
MS

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

VAWD

Bond

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800100345

Application/License No. _____

Owens & Minor Distribution, Inc. (Applicant/Principal) doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5125 Ontario Mills Pkwy., Ontario, CA 91764 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 26, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of August, 2020.

APPLICANT/PRINCIPAL

Owens & Minor Distribution, Inc.

Michael Lorusso
Authorized Representative

SIGNED and SEALED in the presence of:

Nancy Jonkinson
Witness

Witness

SURETY COMPANY

Atlantic Specialty Insurance Company

Anne P
Surety Company's Representative

Anne Potter, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Aklima Noorhassan
Witness Aklima Noorhassan

Sandra Diaz
Witness Sandra Diaz

Countersigned by:

N/A
Nevada Resident Agent

OneBeacon
INSURANCE GROUP

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Debra A. Deming, Sandra Diaz, Cynthia Farrell, Anne Potter, Peter Healy, Susan A. Welsh, Frances Rodriguez, Aklima Noorhassan, Francesca Kazmierczak, Jennifer Jakaitis, Nancy Schnee**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 27th day of August, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara Barrow, Secretary

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

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

State of _____

County of _____

On this ____ Day of _____ in the year 2020 before me, _____ Notary Public, personally appeared _____ who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

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

WITNESS my hand and official seal.

Signature _____

Signature of Notary Public

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

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

State of New York

County of Kings

On this 27th day of August in the year 2020 before me Francesca Kazmierczak , Notary Public, personally appeared Anne Potter, who provide to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that ~~he~~/she/~~they~~ executed the same in ~~his~~/her/~~their~~ authorized capacity(ies), and that by ~~his~~/her/~~their~~ signature(s) on the instruments the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

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

WITNESS my hand and official seal.

Francesca Kazmierczak

Signature of Notary Public

FRANCESCA KAZMIERCZAK
Notary Public - State of New York
NO. 01KA6351499
Qualified in Kings County
My Commission Expires Feb 13, 2021

This document constitutes a list of disciplinary actions taken against Owens & Minor, Inc. and its affiliated companies (collectively, "Owens & Minor"). The applicant provides this document in response to application questions involving disciplinary actions related to the applicant's owners, officers, etc.

Owens &Minor™

Discipline Responses

Company General Comments: Owens & Minor, a Fortune 500 company, has been in the same business since 1882. We operate over 40 distribution centers throughout the country and ship into all states. All of our distribution centers are fully licensed in their respective resident and adjacent states and several hold multiple licenses to ship nationwide. We take legal compliance seriously and employ a number of individuals whose sole focus is to ensure that we follow all applicable state and federal laws and regulations. Changes to laws and requirements are subjects of ongoing vigilance. While we regret that we have been the subject of any discipline, we believe that these instances should be considered in the context of our size and overall operations in a field of enterprise highly regulated by a multiplicity of agencies. This is a comprehensive list of discipline that Owens & Minor Distribution, Inc. has received.

- This is an explanation of a Notice of Fine issued by the Louisiana State Board of Wholesale Drug Distributors against Owens & Minor's Wholesale Distribution Center in St. Rose, Louisiana facility. The citation was issued on April 11, 2002, but related to an inspection conducted on February 1, 2002. The citation referenced violations of regulations on customer license records. All issues had already been rectified to the Department's satisfaction prior to a hearing held on April 9, 2002, and the fine of $5,000 has been fully paid.

- This is an explanation of a citation issued by the California Board of Pharmacy against Owens & Minor's Wholesale Distribution Centers in Livermore and Lathrop, California. The citation was issued in May 2006. The citation referenced violations of regulations regarding timely notification of the Board when a facility's Designated Representative changes. All have been rectified to the Department's satisfaction, and the fine of $500 for both facilities has been fully paid.

- This is an explanation of a report of alleged violations issued by the Florida Department of Health against Owens & Minor's Wholesale Distribution Center in Orlando, Florida. The report was issued in February 2007 and referenced alleged violations of regulations regarding licensing and drug pedigrees. All matters raised in the report were resolved to the Department's satisfaction, the fine in the amount of $285,000 has been fully paid, and the matter is closed.

- This is an explanation of a Settlement Agreement and Disciplinary Order entered into between Owens & Minor Distribution, Inc. and the Missouri Board of Pharmacy. The Settlement, executed in May 2008 references violations of regulations regarding temperature controls and monitoring at its Kansas City, Missouri distribution center. The Company remains fully licensed but was placed on probation for a period of 3 years. There was no fine imposed.

- This is an explanation of a Stipulation Order with the Colorado State Board of Pharmacy concerning Owens & Minor's Wholesale Distribution Center in Denver Colorado. The effective date was November 2, 2009. The Order references a violation of regulations regarding the inadvertent purchase and receipt of prescription drugs on March 5, 2009 from one vendor (Hospira) from a location not licensed by the Board to ship Rx products into Colorado. All issues have been rectified to the Board's satisfaction, and the fine of $5,750 has been fully paid.

- This is an explanation of a Settlement Agreement entered into between Owens & Minor Distribution, Inc. and the Florida Department of Health. The Settlement, executed in July 2010, references violations of miscellaneous recordkeeping, personnel and license verification regulations in Owens & Minor's Wholesale Distribution Centers in Gainesville and Jacksonville, Florida. The Company and those facilities remained fully licensed but were under probation for a period of 2 years. The fine of $12,500 has been fully paid and the probation period passed without incident in 2012.

- On March 15, 2011, Owens and Minor entered into a Consent Agreement with the Louisiana Board of Wholesale Drug Distributors ("Louisiana Board") to resolve a finding in an inspection report dated December 8, 2010 that Owens & Minor received a product from supplier not licensed to sell or ship drugs into Louisiana. The agreed upon fine of $3,500 has been paid and this matter is now resolved to the satisfaction of the Louisiana Board.

- On July 27, 2011 Owens and Minor entered into a Stipulation and Consent Order with the Vermont Board of Pharmacy with regard to the application for a Third Party Logistics license by its facility in Redlands, California - Owens & Minor Healthcare Logistics. The basis of the order was discipline incurred by the company in other states. There was no specific non-compliance with Vermont law, or any other state regulation by any Owens & Minor facility. No fine was imposed. The license was issued subject to compliance with the laws of Vermont and reporting of future disciplinary actions.

- Owens & Minor Distribution, Inc. entered into a Stipulation Order with the Colorado State Board of Pharmacy concerning Owens & Minor's Wholesale Distribution Center in Denver, Colorado. The effective date was August 1, 2012. The Order referenced violations of regulations regarding timely notification of the Board when a facility's Designated Representative changes, and imposed the minimum fine. Colorado law requires that each licensed facility must provide the board with the name of a Designated Representative knowledgeable in regulatory requirements. Those named must meet certain criteria for experience and pass a background check. Changes must be submitted within fourteen

calendar days. However due to an oversight, notice that the Designated Representative had been laid off was not sent for ninety-five calendar days. This oversight was pointed out during a routine inspection in February 2012 and corrected the same day. The Stipulation requires that any future changes be made within prescribed time limits, that Owens & Minor promptly pay all fines and charges, and that it comply with all other applicable laws and regulations. All have been rectified to the Board's satisfaction, the fine of $1,100 has been fully paid and there have been no subsequent incidents of non-compliance.

- In February 2013 The Hawaii Department of Commerce and Consumer Affairs presented Owens & Minor with a Settlement Agreement assessing a fine of $500.00 for having been disciplined in another jurisdiction. No deficiencies were noted in the operations or compliance activities of any specific Owens & Minor distribution center. This was strictly an administrative matter, a fine for being fined essentially. Owens & Minor signed the Settlement Agreement, paid the fine, and the matter is now satisfactorily closed. This action affected no specific Owens & Minor facility.

- In August of 2012 Owens & Minor took over management of a hospital customer's internal warehouse and medical-surgical product distribution activities to the hospital's facilities and clinics in and around Burlingame, Ca. The facility was not licensed by the California Board of Pharmacy at the time management responsibilities changed. Accordingly, Owens & Minor submitted an application for licensure, and during the pre-licensing inspection, the Board representative took note of the presence of prescription drugs and devices that had been received and stored in the warehouse prior to the hospital's decision to outsource this activity to Owens & Minor. No other deficiencies or issues were identified, and the Board issued Owens & Minor a Wholesale Distributor's license shortly thereafter. In March of 2013, the Board issued Owens & Minor a citation for operating an unlicensed facility, assessing a fine of $2,500, but imposing no other sanctions. All issues have been rectified to the Board's satisfaction, the fine has been fully paid, and the matter is now closed. This action involved only the Owens & Minor distribution in Burlingame CA, and no others.

- This is notice of an action by Kentucky Board of Pharmacy. In December 2014, Owens & Minor entered into an Agreed Order with the Board of Pharmacy concerning Owens & Minor's tardy formal notice to the Board of its closing of a wholesale distribution center in Louisville, KY in 2013. The Board assessed a fine of $500.00. Owens & Minor signed the Order, paid the fine and the matter is now satisfactorily closed.

- In June, 2017, the Hawaii Department of Commerce and Consumer Affairs presented Owens & Minor with a Settlement Agreement assessing a fine of $250.00 for discipline received from the Colorado State Board of Pharmacy for its Denver, CO facility due to a tardy notification of a change in Designated Representative. This was strictly an administrative fine for being disciplined in another jurisdiction. Owens & Minor signed the Settlement Agreement, paid the fine, and the matter is now satisfactorily closed. It should also be noted that the Honolulu facility closed on December 31, 2016.

- On April 26, 2018, Owens & Minor Distribution, Inc. entered into a Settlement Agreement with the State of Florida Department of Business & Professional Regulation regarding the tardy formal notification to the Board of a change in Designated Representative and the imposition of discipline by another state, also regarding a tardy notification of change in Designated Representative. The Department assessed a fine of $2,250.00 and determined that the agreement will not be deemed to constitute discipline within the meaning of Florida pharmacy laws. Owens & Minor signed the Order, paid the fine and the matter is now closed.

- On November 28, 2018, Owens & Minor Distribution, Inc. entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the tardy formal notification to the Board of a change in Designated Representative as well as failure to review its policy and procedure manual. The Department assessed a fine of $6,900.00, and the matter is now closed.

- On February 25, 2019, Owens & Minor received a citation issued by the California Board of Pharmacy against Owens & Minor's Louisville facility. The citation referenced violations of regulations regarding timely notification of the Board when a facility's Designated Representative changes. No fine has been assessed with the citation and no proof of abatement has been ordered. The matter is now closed.

- On March 19, 2019, the Florida Department of Business & Professional Regulations presented Owens & Minor with a Settlement Agreement assessing a fine of $3,000.00 for discipline received from the Colorado State Board of Pharmacy for its Denver, CO facility due to a tardy notification of a change in Designated Representative. This was strictly an administrative fine for being disciplined in another jurisdiction. Owens & Minor signed the Settlement Agreement, paid the fine, and the matter is now satisfactorily closed.

- On April 19, 2019, the Colorado Department of Regulatory Agencies, Division of Professions and Occupations presented Owens & Minor with a Letter of Admonishment recognizing that Owens & Minor failed to timely submit an application and fee for a change of Designated Representative for the Chicago, IL facility. This was strictly an open public record and reportable action and no such fine was given. Owens & Minor did not initiate formal disciplinary hearings to adjudicate the conduct and has accepted the letter for public record. This matter is closed.

- On December 11, 2019, the Colorado Department of Regulatory Agencies, Division of Professions and Occupations presented Owens & Minor with a Stipulation and Final Agency Order regarding the tardy formal notification to the Board of a change of Designated Representative. The Department assessed a fine of $5,000.00. Owens & Minor signed the Stipulation agreement, paid the fine, and the matter is now satisfactorily closed.

- On September 10, 2020, the Colorado Department of Regulatory Agencies, Division of Professions and Occupations presented Owens & Minor with a Stipulation and Final Agency Order regarding the failure of the Designated Representative to review, sign and date its policy and procedure manual within a year of the previous date it was reviewed. The Department assessed a fine of $1,150. Owens & Minor signed the Stipulation agreement, paid the fine, and the matter is now satisfactorily closed.

- On December 22, 2020 Owens & Minor Distribution, Inc. entered into a Stipulation and Final Agency Order from the State of Florida, Department of Business & Professional Regulation under Case #'s 2020-007156; 2020-007158; 2020-007161; 2020-007162 for the 2019 Colorado State Board of Pharmacy discipline that was issued for failure to notify within 30 days of a change of DR at the facility located at 473 Tower Blvd., Carol Stream, IL 60188. In lieu of a hearing, the Board resolved this case by means of a stipulated agreement pursuant to the following terms: Settlement in the amount of $5000.00. Owens & Minor signed the Order, paid the fine and the matter is now satisfactorily closed.

Officer Signature

2-16-2021
Date

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH 00999

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

- ☐ Publicly Traded Corporation – Pages 1,2,3,4
- ☐ Partnership - Pages 1,2,3,7,8
- ☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
- ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: SRCL Expert Solutions LLC

Physical Address: 2670 Executive Drive Suite A

City: Indianapolis State: IN Zip Code: 46241

Telephone Number: (317)504-9980 Fax Number: (888)345-4679

Toll Free Number: _____

E-mail: Licensinghelp@sedgwick.com Website: https://www.sedgwick.com/brandprotection

Facility Manager: Andrew Hindal

Professional qualifications and experience of facility manager: See attached resume for Andy Hindal

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers

☐ Other: _____

Type of Products to be handled or wholesaled by firm:

- ☒ Legend Pharmaceuticals, Supplies or Devices
- ☐ Poisons or Chemicals
- ☒ Controlled Substances (include copy of DEA)
- ☐ Other: _____
- ☒ Hypodermic Devices
- ☒ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☒ No ☐
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

See attached Client List

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Diane Ryker
Print Name of Authorized Person

4/22/2021
Date

Board Use Only Date Processed:_____ Amount: $500 Check # 597422 ✓

Processed mw 5/19

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Sedgwick Claims Management Services, Inc.

Mailing Address: 8125 Sedgwick Way

City: Memphis State: TN Zip: 38125

Telephone: 901-415-7400 Fax: 901-415-7409

Contact Person: Diane Ryker Phone 317-504-9980

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation? NA

a) _____
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. NA

3) What was the price paid per share? NA

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation

List of officers and directors Attached

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

License Number	Expire Date
48002437A	09/30/2022

SRCL Expert Solutions, LLC

Eric J. Holcomb
Governor
State of Indiana

Deborah J. Frye
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

License Number	Expire Date
48002437A	09/30/2022

SRCL Expert Solutions, LLC

Signature _____

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

CSR

Registration Number	Expire Date
61102090B	12/31/2021

DRUG SCHEDULES

1	2	2N	3	3N	4	5
Yes	Yes	Yes	Yes	Yes	Yes	Yes

SRCL Expert Solutions, LLC

Eric J. Holcomb
Governor
State of Indiana

Deborah J. Frye
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

CSR

Registration Number	Expire Date
61102090B	12/31/2021

SRCL Expert Solutions, LLC

Signature

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SRCL EXPERT SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SRCL EXPERT SOLUTIONS, LLC" WAS FORMED ON THE FIRST DAY OF JULY, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7495217 8300

SR# 20211310160

Authentication: 202976036

Date: 04-15-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

SRCL Expert Solutions, LLC

100% owned by Sedgwick Claims Management Services, Inc.

Officers: Kimberly D. Brown – President

Henry C. Lyons – Executive Vice President, Chief Financial Officer and Treasurer

Stephen R. Hurley – Senior Vice President and Secretary

Managers: Kimberly D. Brown

Stephen R. Hurley

Facility Manager: Andy Hindal – 317-519-2519

Designated Rep: Diane Ryker - 317-504-9980

SRCL Expert Solutions, LLC

100% owned by Sedgwick Claims Management Services, Inc.

Officers: Kimberly D. Brown – President

Henry C. Lyons – Executive Vice President, Chief Financial Officer and Treasurer

Stephen R. Hurley – Senior Vice President and Secretary

Managers: Kimberly D. Brown

Stephen R. Hurley

Facility Manager: Andy Hindal – 317-519-2519

Andrew Hindal

[redacted]Brookstone Place Zionsville, IN 46077 [redacted] [redacted]

SUMMARY OF QUALIFICATIONS

- ❖ Over 10 years of progressive leadership experience in GMP and SOX regulated environments, focused on large, diverse team development, exceeding customer expectations, forecasting and business metrics/analytics.
- ❖ Operating knowledge of Windows, Microsoft Word, Excel, PowerPoint, Access, Outlook, Visio, Salesforce, ADP, Peoplefluent, and multiple, web based pharmaceutical and data processing systems.
- ❖ Obtained certifications for various jobs including Continuous Improvement, Team Facilitation, Leadership, CPR Instructor, and multiple military certifications.

WORK EXPERIENCE

2017-Present Director, Operations – Stericycle: Lead all operational activities, including product processing, DEA oversight for multiple divisions, print production, fulfillment, destruction, shipping and receiving for multiple facilities encompassing 350,000+ square foot processing and warehousing facility.

- Complete responsibility over forecasting, P&L and budget adherence for all subordinate teams encompassing over $35,000,000 in annual revenue.
- With executive team, initiate new programs, analyze budget and operational impacts, and afford knowledge and experience of front line processes to drive informed decision making on pricing and operational capabilities.
- Worked with internal IT resources and external vendors to design and create a new processing system, warehouse management system and destruction module creating previously unrealized efficiencies through automation, providing end to end systemic visibility of inventory and incorporating real time instruction to reduce training requirements.
- Continuously worked to identify high performing team members for development purposes to recommend for additional training or promotion opportunities.
- Negotiated, secured and began operations in an additional 80,000 square foot facility in a 72 hour timeline in order to begin receiving 2,000 additional pallets of product.

2015-2017 Warehouse Manager - Stericycle: Provided leadership to recall, returns and DEA product processing, as well as shipping and receiving with a total workforce of 80-100+ employees, with up to $15,000,000 in annual revenue.

- Absorbed the responsibilities of 3 managers over a period of 2 years, while also mentoring and promoting internal resources in order to prevent gaps in leadership and processes.
- Brought staff to operating and effectiveness levels which provided the opportunity to step away from current role for 2 months to assist with a $30,000,000 recall event which had direct impact on meeting corporate revenue and bottom line profit goals.
- Designed process flows, provided real time analytics, and deep dive analysis for various business units and activities reducing cost and increasing profit in the face of substantial obstacles, both economic and in regards to internal infrastructure.

- Identified and realized over $1,500,000 in uncollected credit for Returns segment.

2012-2015 Operations Manager - Returns - Stericycle: Managed both returns segments, encompassing 60+personnel and $5,000,000+ in annual revenue.

- Worked with multiple departments to purge undocumented practices and put "tribal knowledge" into Standard Operating Procedures.
- Consolidated from two shifts down to one, predicting annual savings of $500,000, through a redesign of warehouse workspace, process flow improvements and elimination of redundant activities.
- Created new forecasting and revenue models improving monthly forecast capabilities.

2010-2012 Warehouse Operations Supervisor - Stericycle: Responsibility over 20-40 processors and team leads, managing daily warehouse operations, including production, quality and resource management.

- Instituted six sigma/lean process improvements to standardize processing area and increase production.
- Took initiative to learn and own all aspects of Trade Returns business beyond specific team functions.

2007-2014 Platoon Sergeant - Infantry – USMC Reserve: Led up to 45 Marines and Sailors in all aspects of training in preparation for combat and support operations.

- Directed multiple teams in engagement of diverse, combat oriented activities.
- While deployed overseas, maintained professional character in high pressure situations, in culturally diverse, austere environments.
- Consistently maintained accountability of $2,000,000 worth of equipment.
- Fulfilled responsibilities of both Platoon Commander and Platoon Sergeant for multiple months during periods of personnel limitations.

2005-2006,2008-2009 Intern Supervisor/Program Director – Lake Ann Camp: Provided daily direction and guidance to intern team while providing great customer experiences to various guest groups in an overnight camp setting

- Pioneered a new opportunity focused on an emerging market, providing a new revenue stream which continues today.
- Sought continuous improvement throughout tenure, pushing for new program techniques focused on training and development
- Performed a variety of tasks including team facilitation, training, event management, and facility maintenance.

EDUCATION

Master of Arts, Organizational Leadership, 2014
Clarks Summit University Graduate School, Clarks Summit, PA
Bachelor of Science, Bible, 2005
Clarks Summit University, Clarks Summit, PA

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 23260709

Application/License No. _____

SRCL Expert Solutions (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2670 Executive Drive, Suite A, Indianapolis, IN 45241 (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 12, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 12 day of March, 2021.

APPLICANT/PRINCIPAL

SRCL Expert Solutions

Authorized Representative

KAREN HUGGEMANN BOOM NOTARY PUBLIC STATE OF TENNESSEE COUNTY OF SHELBY My Comm. Expires July 3, 2021

3-12-2021

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Maureen McNeill, Attorney-in-fact & NV Non-Resident Agent License #3423463

print name

SIGNED and SEALED in the presence of:

Witness Bianca M. Phillips

Witness Cori Wilson

Countersigned by:

N/A

Nevada Resident Agent

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Maureen McNeill

, Individually

of Philadelphia, Pennsylvania, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts –

Surety Bond Number: 23260709
Principal: SRCL Expert Solutions
Obligee: Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T. Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires

March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 12 day of March, 2021.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

Authorizing By-Law

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

NABP ACCREDITED
DRUG DISTRIBUTOR

Sedgwick Claims Management Services, Inc

located at

2670 Executive Dr, Ste A, Indianapolis, IN 46241

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

4/22/2020 - 4/21/2023
Period of Accreditation

882

3M
4E Brands North America
AA Pharma Inc
Abbott Diabetes Care
ABBOTT NUTRITIONAL
ABC Chemical Company
Academic Network
Acclarent
Acist Medical
Acme Pharmaceutical
Acorda Therapeutics
Actavis
Acuity Lighting
Acuity Specialty-Chemical
Acumed
Advance Sterilization Products
Advanced Accelerator Applications
Advanced Compounding Pharmacy
Advanced Sterilization Products
Ainsworth Pet Nutrition
Ajinomoto Windsor
Akebia Therapeutics
Alarm Detection Systems, Inc.
ALBERTO CULVER
ALBERTO CULVER CANADA
Alcon Labs
Alembic Pharmaceuticals
Alere
Alere Scarborough, Inc.
ALKERMES
All Clear ID
All-Clad
Allergan Inc
Alleson Athletics
Almark Foods
Alpine Fresh
Altria
Altria Canada
Amazon
Ameditech
American Health Packaging
American Licorice Company
American Outdoor Brand / Crimson Trace
American Pharmaceutical Ingredients
American Red Cross
Ameridose
Amgen, Inc.

Amneal Pharmaceuticals LLC
AMO Canada Company
AMO, Inc
Amring Pharma
AmTRAN Technology Co
Amy Apothecary
Amylin
Amys Kitchen
Anazao Health
Andrx Laboratories
ANHEUSER-BUSCH LLC
ANIMAS
ANIXTER INC
Anspach
APOTEX
Appeeling Fruit Inc
Apperley Holdings Pty Ltd
Aptalis
Aqua Leisure Industries
Arbor Pharmaceuticals
Arcelik A.S.
Ariad Pharmaceuticals
Arlo Technologies, Inc.
Astellas Pharma Canada, Inc
Astellas Pharma US Inc
AstraZeneca Pharmaceuticals
Atwood Mobile Products
Aurobindo Pharma Ltd
Avanos Medical Inc
AVENTIS BEHRING
Aventis Pharmaceuticals
Aventis Pharmaceuticals Products Inc.
Aveva Drug
Aviva Sports Inc
Ayablu, Inc
B&G Foods North America
Baby Matters LLC
Bar-S Foods
Bauer
Bausch and Lomb
BAUSCH and LOMB CANADA
Bausch Health
Baxalta
Baxter BioScience
Baxter Healthcare
Baxter Healthcare Corporation
Bayer, Inc. (Canada)

BeaMonstar Products
Becton Dickinson
Becton Dickinson - Life Science
Bellisio Foods Inc.
BEST BUY STORES
Beyond Beter Foods
Bic World
Bio Life Sciences Corp (Canada)
BIOLOK
Biomet 3i
BioSound
Biospecifics Technology Corp
BIOVAIL CORPORATION
Biovail Pharmaceuticals Inc
Bioventus
Blacksmith Brands
Blue Bell
BLUE BUFFALO CO (RQA)
Blue Buffalo. Ltd.
Blue Chip Patient Recruitment
Body Plus-Canada
Boiron Inc.
Boku International
Bosch
Bracco Diagnostics, Inc
Braintree Laboratories
Bristol Myers Squibb
BWI
C H Robinson
Cadence Gourmet
Cadence Pharmaceuticals
CALLAWAY GOLF
Camber Pharmaceuticals
Canadian Mock Event
CAPCO USA, Inc.
Caraco Pharmaceuticals Ltd.
CareFusion
Carl Zeiss Meditec, Inc.
Cedar Crest Specialties
Censea
Cephalon
Chelan Fresh Marketing
Chicken of the Sea International
Chobani
CibaVision
Cintas Corp.
Clif Bar

Clorox
Codman
Colomer
Columbia Marketing International
Columbia Sportswear
ConMed Corporation
ConvaTec
Cook Medical
Cordis
Costco
Covance
Covidien
Covidien Vascular Therapies
Cree
Cree Canada
CRF Frozen Foods
Crowell and Moring LLP co DuPont
Curbell
Cynosure
Daiichi Sankyo
Dairy Farmers of America
Dairy Queen
Daniele Foods
Dawn Food Products
Decathlon
Delifish/Marine Harvest
Delonghi (OUS)
Delta Pharma, Inc.
DePuy
DePuy Mitek Sports Medicine
DePuy Synthes Spine
Designs Direct LLC
DevaCurl
Dexcom
DEY L.P.
Diamondback Drugs of Delaware, LLC
Dicks Sporting Goods
Digestive Care Inc
Dill Air Controls
Diono
Direct Energy
Directed Electronics, Inc.
Directed LLC
Discovery Labs
DJO Global
Doki Technologies
Dole Packaged Food

Dometic Corporation
Dotta Foods International
DOUBLE INSIGHT
Dr. Praegers Sensible Foods
Dr. Reddys Laboratories, Inc.
Draeger Medical, Inc
Drive DeVilbiss Healthcare
Duraflame, Inc.
Edgewell Personal Care (Canada)
Eisai
Elan Corporation, plc
Elanco Animal Health
Eli Lilly and Company
Ellman International, Inc
Emerson Electric
ENDO PHARMACEUTICALS INC
Environmental Solutions
Ethex Corporation
Ethicon
Ethicon Endo-Surgery
Fagron Sterile Services LLC
Ferring Pharmaceuticals Canada
Ferring Pharmacuticals
Fieldbrook Foods
Fisher and Paykel
Fisher Price
Fitbit Inc
Flir
Flushmate (Dentons)
FMC
Focus Laboratories, Inc.
Focus Products Group International, LLC
Foreign Tire Sales Inc
Forest River Inc.
Fosun Pharma
Fougera Pharmaceuticals
FPZ S.p.A.
Franklin Corporation
Freeze-Dry Foods
Fresh & Easy
Frontida BioPharm, Inc
FSC Laboratories
Fuji Film
Fuji Food Products, Inc.
G & W Laboratories
G Mason Group
GE Appliances

General Electric
Genomma Labs
Genzyme Corporation
Georgia-Pacific Consumer Products LP
GFG Management
Giggles International Ltd
Gilead Sciences Inc.
GlaxoSmithKline
GlaxoSmithKline - Canada
Glenmark Generics Inc, USA
Goodman
Google, Inc
GPSUS
GPSUS-1
GPSUS-2
GPSUS-3
Graco Baby Products
Great Spirits Baking Company
Greatbatch Medical
Gree Electric Appliances
Green Cuisine
Green Space Brands Inc. CA
Greenberg Traurig LLC
Guthy-Renker
Hachette Book Group
Haemonetics
Hain Celestial
Halyard Health
Harley Davidson
Hasbro
HeartSine Technologies
HeartWare
Heinz Canada
HemoCue
Hercules Tire & Rubber Company
Heritage Pharma
Hillrom
Hitachi
Home Depot
Honeywell Industrial Safety
Hospira Canada
HOSPIRA INC
Hospira Inc. - Device
Hot Mamas Foods
House of Thaller
HP INC
Hudson Global

Hu-Freidy
Humanscale Corp
Hylands
Hyman, Phelps, and McNamara
Hyso LLC
Hy-Vee Inc.
ICU Medical CA
ICU MEDICAL INC
IDEXX
Ignite USA
IKEA
IKEA Canada
IMPAX LABORATORIES INC
INNOVATION VENTURES
Insight Pharmaceuticals Corporation
Insys Therapeutics, Inc.
Integrity Pharmaceutical Corporation
Invacare
IOVATE HEALTH SCIENCES RESEARCH INC
Janssen (DO NOT USE)
Janssen Pharmaceutical Research and Development
Japan Tobacco International
Jel Sert
JEMPAK GK INC.
JHP Pharmaceuticals, LLC
JNJ Consumer INC Clinicals
JOHNSON & JOHNSON CANADA
Johnson & Johnson Consumer, Inc
JOHNSON AND JOHNSON CANADA
Johnson and Johnson Consumer Companies, Inc.
Johnson Outdoors
K9 Natural Food Ltd.
Kantar Health
KARL STORZ
Kaz Canada
Kaz USA Inc A Helen of Troy Company
Kelloggs
Kenra Professional
Keryx Biopharmaceuticals, Inc.
KevinsCorp
Kidde
Kids II
Kimberly Clark Corporation
King Pharmaceuticals
Klean Kanteen
Knape and Vogt
Konica Minolta Healthcare Americas Inc

Kos Pharmaceuticals, Inc.
Kraft Foods Global, Inc.
Kremers Urban Pharmaceuticals Inc
Kronos
KT Health
La Terra Fina
Laboratoire Riva Inc.
Laerdal Medical Canada
Laerdal Medical Corporation
Land O Lake
Lansinoh Labs
LE Bar
Lemur Group Inc
Lenny & Larrys
Lerado Success
Letco Medical, LLC
Life Fitness
Lifescan
Lifescan (Canada)
Linear
Lippert Components
Loblaw Companies Ltd.
LogicData
LoJack
Lorex Technology
Louis Hornick and Company, Inc
Louisville Ladders
Lumber Liquidators
Lumicentro
Mabe
Major Pharma
Mallinckrodt
Maple Chase Company
Marine Harvest
MARS
MARS Canada Ltd
Mars Chocolate North America
Mars Retail Group
MAYNE PHARMA USA
MC Commercial Inc.
MCCAIN FOODS, INC
McConnells Fine Ice Creams
McDonalds
McNeil Consumer and Speciality Pharmaceuticals
McNeil Nutritionals
McNeil-PPC, Inc
McNeil-PPC, Inc.

Meda Pharmaceuticals
Medcomp
Medela, Inc
Medical Device Client Inc.
Medicis
MedImmune
Medline
Medtronic
Medtronic Neuromodulation
Megadyne Medical
Mentor
Merck and Co.
Merck Canada
Merge Healthcare
Meridian Medical Technologies, Inc.
Merit Medical
MGA Entertainment, Inc.
Michael Foods
Michaels Stores
MicroAire Surgical Instruments
Microsoft Corporation
Millennium Pharmaceuticals
MILLENNIUM PHARMACEUTICALS, INC
Miniland Educational
MixBin Electronics, LLC
Miza Pharmaceuticals USA Inc
Mohawk Group, Inc.
Monoprice
MOORECO
Morton Grove Pharmaceuticals
Motorola Solutions
Mylan Institutional
Mylan Pharmaceuticals Inc
Mylan Pharmaceuticals ULC Canada
National Beef
National Steak and Poultry
Natural Solutions for Life
Nest Collective
Nestle USA
Nestle Waters
Neurocrine Biosciences
Neutrogena
New England Consulting Group
New Haven Moving Equipment
New Mexico Dept of Health
New Seasons Market LLC
Niagara Bottling LLC

Nidec Motor
Nipro Diagnostics
Nissan
NitroMed
NNC Group / Client Survey
No estimate assigned
Nora Apothecary
Noramco, Inc.
Norcraft Industries
Northern Star Foods
NorthStar Healthcare
Novartis Animal Health
Novartis Pharma
Novartis Vaccines and Diagnostics, Inc.
Noven Pharmaceuticals
Novitium Pharma
Nu-Pharma Inc
Nutrition Resource Services, Inc.
NVIDIA
Nycomedus
Oakland Law Group
Oakland Law Group, LLC
Obagi
Ocean Beauty Seafoods LLC
OPW
Orexigen
Orval kent food company
Our Pets
Owens & Minor
OXMOOR HOUSE INC
P and G Pharmaceuticals
P3 International Corp
Pacific MSO, LLC
Packaging Tape Inc
Paddock Laboratories
PAR Pharmaceutical
Parragon Publishing Ltd.
Pass & Seymour/Legrand
Patterson Medical Supply Inc
PD SIXTY DISTRIBUTOR INC
PDL BIOPHARMA
Pedego, Inc.
Pepsico
Performance Health
Perrigo
PetSmart
Pfizer Canada

Pfizer Inc.
Pfizer, Inc.
Pharma Fab
Pharmavite LLC
PHILIPS HEALTHCARE
Philips Healthtech
PHILIPS MEDICAL SYSTEMS
Plum Organics
Polaris
Post Consumer Brands
PPSWG
PPTA
Prasco Labs
Pressure Products
Primark
Primus Pharmaceuticals, Inc.
Prinston Pharmaceuticals
Professional Arts Pharmacy
Prous Science SAU
PSGA
PSS WORLD MEDICAL
Purdue Pharma
Purina
Qcore
QTrade Teas and Herbs
Quidel
Ramar Foods
Ranbaxy
RapalaUSA
Razor
RB Health US LLC
Real Clean
Real Flame
Reckitt Benckiser-Canada
Red24
Resers Fine Foods
ResMed
Respironics
Restoration Hardware
Rich Products Corp
RJ Reynolds
Robertshaw Controls Company
Robin America
Roche Diagnostics
Roche Diagnostics Canada
Roche Pharmaceuticals
Rock Hard Labs

Rockline Industires
Rose Acre Farms
RQA, Inc.
RRD
Rugby Pharma
Ryt-way Industries, LLC
S Toys Holdings LLC
SA Consumer Products
Sahn Designs
Salix
Samsung Electronics
Samsung Electronics CA
Sandoz
Santa Cruz Bicycles
SargentoFoods Inc.
SCA Pharma
Schell & Kampeter - Diamond Pet
Schering Plough
Schwabe North America Inc
Schwarz USA
Sea Port Products
Sealed Unit Parts Co., Inc
Seattle Genetics
SETTON INTL FOODS INC
Shenandoah Growers, Inc.
Sherwin Williams
Shionogi
Shire
Shoes for Crews
Shoinogi USA, Inc.
SHOPPERS DRUG MART CORP
Siemens Healthcare Limited Canada
Siemens Medical Systems
Sigma
Signature Club A Ltd.
Simply Fresh Foods, Inc
Smith & Wesson
Smith and Nephew
Smiths Medical
Solid Gold
Solta Medical
Solucionces Cosmeticas/Euro Cosmetics Intl
SonoSite
Sorin Group USA, Inc.
South Shore
Southwest Greene International Inc.
Southwire

Specialty Compounding
Spectrum Brands
Splendid Products
St. Jude Medical
Starbucks
Stemilt
Stericycle
Sterilmed
Steve Madden LTD
StrongPak
STRYKER BIOTECH
Stryker Endoscopy
STRYKER INSTRUMENTS
Stryker Ortho
Stryker Sustainability Solutions
Subaru
Sunovion Inc.
Superior Foods
Supernus Pharmaceuticals
Suzuki Motor of America
Synthes
Synthon Pharmaceuticals LTD
Takeda
TALKING RAIN BEVERAGE CO
Tampa Bay Fisheries
TAP
Taylor Company
Teavana
Teikoku Pharma
Tempur Sealy
Terumo
Terumo Medical
Terumo Medical Corporation
The Communications Department, Inc.
The Florida Brewery, Inc.
The Harvard Drug Group LLC
The Honest Company
The Integer Group
The Yankee Candle Company
The Ziegenfelder Company
Theravance Biopharma US
THERMO FISHER SCIENTIFIC
Ther-Rx Corporation
THOR INDUSTRIES
Thorne Communications
Titan International
TK Holdings

Topps Meat Company
Townsend Farms
Triangle Tube
Tribe Mediterranean Foods
Triple 8
Trividia Health
Trojan Technologies
Tytek Medical
UCB, Inc.
UDL Laboratories, INC
Ultimark Products LLC
Unilever
Unipharma, LLC
Unique Pharmaceuticals, Ltd.
United SCI
United Therapeutics
Upsher-Smith Laboratories, Inc.
Valeant Canada
Valeant Pharmaceuticals
Varian Medical Systems
Vendini
Vensun Pharmaceuticals
Ventana Medical Systems, Inc.
Verathon
Verizon Wireless
Vertex Pharmaceuticals
VI Technologies
Victory Innovations
Viking Range Corporation
Village Fertility Pharmacy, Inc
VISTAKON
Vitamix Corp
Volcano Corp
Vornado
Vyaire Medical
Warner Chilcott
Watson Laboratories, Inc.
Wawona Packing Company
WD-40
Webasto Charging Systems ,nc.
Wedgewood Pharmacy
Welch Allyn
WellPet
WellSpan Health
Whirlpool
Wild & Wolf
WL Gore

WYETH
Xanodyne Pharmaceuticals
Xcel Pharmaceuticals
YC Rubber
Yokohama
Yokohama Canada
Yokohama PMC
YSN Imports Inc.
Zak Designs
Zebra Technologies
Zimmer Biomet
Zimmer Dental
ZIMMER, INC
Zoetis
ZYDUS

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Amicus Therapeutics US, LLC

Physical Address: 3675 Market Street

City: Philadelphia State: PA Zip Code: 19104

Telephone Number: 215.921.7600 Fax Number: _____

Toll Free Number: _____

E-mail: GCoffice@amicusrx.com Website: www.amicusrx.com

Facility Manager: Brian Venturi

Professional qualifications and experience of facility manager: _____
See attached resume.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Daphne Quimi — Daphne Quimi — 8-April-2021

Print Name of Authorized Person — Date

Board Use Only	Date Processed: 5/24/2021	Amount: 500 Check # 3543417

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: DE

Parent Company if any: Amicus Therapeutics, Inc.

Corporation Name: Amicus Therapeutics US, LLC

Mailing Address: 3675 Market St.

City: Philadelphia State: Pennsylvania Zip: 19104

Telephone: 732-666-5458 Fax: _____

Contact Person: Brian Venturi

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 2/4/2002

Registration number issued: See Attached

Stock Exchange: FOLD

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

Certificate of Record

Certificate No. 9500000218

Drug & Device Registration

555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

Category:

Office/Corporate Location
No product onsite

AMICUS THERAPEUTICS US, LLC
3675 MARKET STREET
PHILADELPHIA, PA 19104

The above business is recognized by the Department of Health as an entity that is doing business in the Commonwealth of Pennsylvania related to pharmaceuticals, medical devices, or cosmetics for which said entity **does not** physically handle, possess, transfer, manufacture, distribute, or retail pharmaceuticals, medical devices or cosmetics at the location on the certificate of record.

Issuance Date: January 21, 2021

Expiration Date: The Last Day of February, 2022

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Rachel L. Levine, MD
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMICUS THERAPEUTICS US, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6575746 8300

SR# 20210284992

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202410315

Date: 02-01-21

Amicus
Therapeutics

Description of Operations

Amicus Therapeutics US, LLC. ("Amicus") is a Virtual Manufacturer. Amicus' products are manufactured by the following contract manufacturer...

Almac Pharma Services
22 Seagoe Industrial Estate
Craigavon | BT63 5QD | United Kingdom
FDA Establishment Number: 3004444888
DUNS: 233170864

Amicus will utilize the following (3PL) to distribute their products...

ICS / Amerisource Bergen
420 International Blvd, Suite 500
Brooks, KY 40109
FDA Establishment Number: 3002478693
DUNS: 832820588

Amicus' hours of operation are 9:00am-5:00pm Eastern Standard Time.

Amicus Therapeutics

Ownership

Amicus Therapeutics US, LLC., is a Delaware filed corporation
3675 Market Street
Philadelphia, PA 19104
Phone: 908-500-7230

... is the wholly owned subsidiary of Amicus Therapeutics, Inc., a Pennsylvania based pharmaceutical company publicly traded on the NASDAQ as "FOLD".

Amicus Therapeutics, Inc.
3675 Market Street
Philadelphia, PA 19104
908-500-7230

Corporate Officers

Bradley Campbell, President
3675 Market Street
Philadelphia, PA 19104
Phone: 908-500-7230
Ownership Percentage: 0%

Ellen Rosenberg, Corporate Secretary
3675 Market Street
Philadelphia, PA 19104
Phone: 908-500-7230
Ownership Percentage: 0%

Daphne Quimi, Treasurer
3675 Market Street
Philadelphia, PA 19104
Phone: 908-500-7230
Ownership Percentage: Less than 1%

Brian H. Venturi, M.S., PMP, CSCP, CSSGB

Princeton, NJ 08540-3221
Phone: +1 201-396-1086
E-mail: [redacted]
LinkedIn: www.linkedin.com/in/BrianVenturi

Summary: Highly motivated, innovative, results oriented, supply chain project manager with over 15 years of proven success directing multi-million dollar global projects. Background includes launching a high-productivity cross-functional project team, developing a global strategy, and then implementing that strategy in more than 70 countries. As a critical thinker and an adept negotiator with a broad range of industry experience I excel at enhancing partnerships, challenging outdated concepts, and exceeding customer expectations.

Education:

M.S. Biochemistry. The University of Scranton, Scranton, Pennsylvania.
B.S. Biology. The University of Scranton, Scranton, Pennsylvania.
B.A. Philosophy. The University of Scranton, Scranton, Pennsylvania.

Professional Experience:

Amicus Therapeutics, Inc., Associate Director, Distribution and Logistics—Technical Operations (Full-time)
Princeton, NJ
December 2017 – Present

Manage supply chain activities globally for Amicus Therapeutics, Inc., a world renowned biotechnology company founded by serial entrepreneur John F. Crowley. Amicus employs approximately 300 people and specializes in rare and orphan diseases.

- Designed and implemented a serialization program for Amicus commercial drug product that is compliant with the European Union's Falsified Medicines Directive (FMD) and the Drug Supply Chain Security Act (DSCSA)
- Oversaw the commercial coding standards for Global Trade Item Numbers (GTINs), National Trade Item Numbers (NTINs), Serial Shipping Container Codes (SSCCs), and National Healthcare Reimbursement Numbers (NHRNs) at the each, case, and pallet levels
- Established serialization legal agreements with the European Medicines Verification Organization (EMVO) and with over 21 European National Medicines Verification Organizations (NMVOs) to which we distribute serialized drug product
- Conducted TraceLink Serialized Operations Manager (SOM) transfers from our packager to our 3PL in the EU and in the US
- Employed the TraceLink SOM disaggregation and decommissioning functionality to update the aggregation tree for product removed for samples, testing, or other non-serialized use.

Professional Experience (continued):

- Partnered with Information Technology (IT) to prepare a Computer Systems Validation (CSV) plan for implementing TraceLink; a cloud based serialization solutions provider. The CSV process included development of a Master Validation Plan, a User Requirements Specification (URS), a URS Risk Assessment, a Validation Protocol with executable Test Scripts, and a Validation Summary Report. I also oversaw ongoing serialization computer system re-qualification activities
- Designed a more efficient system for managing commercial drug product labeling, which included the implementation of an electronic document management system, procedures, and a global training package
- Created a 650+ line MS Project plan to outline all Biologics License Application (BLA) related distribution testing and child resistant cap testing.
- Oversaw distribution qualification activities in preparation for the launch of our first commercial biologic product engineered for the treatment of Pompe disease. Activities – as required for the Biologics License Application (BLA) – include thermal and physical testing of dry ice drug substance and refrigerated drug product insulated containers, shock and vibration testing on lyophilized drug product vials, and CO_2 ingress testing on 5L drug substance bottles.
- Conducted a Hazard and Operability Study (HAZOP) to assess the supply chain risk for the storage and distribution of our AT-GAA biologics product launch
- Oversaw the packaging design for our AT2221 small molecule encapsulated chaperone, which included cross-functional alignment on the primary package, desiccant, coil, tamper evident induction seal, cap, number of capsules per bottle, labeling specifications, carton design, and case quantities.
- Undertook a stretch assignment as Interim Director, Clinical Supply Chain. In this role I managed the supply of Investigational Product (IP) through all stages of clinical development including packaging, labeling and distribution. I also advise Clinical Operations and clinical sites on all aspects of IP and comparator products
    - Responsible for the development and leadership of Amicus Global Clinical Supply, which includes two supply mangers and a demand manager / master scheduler
    - Oversee two clinical programs which include AT1001 for Fabry disease and AT-GAA for Pompe disease
    - Administer the design, development, User Acceptance Testing (UAT), launch, and maintenance of clinical trial Interactive Response Technology (IRT) systems including four Everest systems and two Almac IxRS systems
    - Coordinated with internal and external stakeholders to deliver clinical drug product under emergency use law to a 14 month old patient in Germany. This was the first such expanded access emergency use request in our company's history and we delivered the drug to the treating physician in three business days
    - Successfully managed Suspected, Unexpected, Serious Adverse Reaction (SUSAR) reports by unbinding the subject treatment assignment to Pharmacovigilance while carefully maintaining the blind with Clinical Operations stakeholders
    - Supervised activities for our most complex trial, ATB200-03. This is a phase 3 double-blind randomized trial to study the efficacy and safety of intravenous ATB200 co-administered with oral AT2221 in adult subjects with Late Onset Pompe Disease (LOPD) compared with Alglucosidase Alfa (Myozyme).
    - Partnered with the Almac IxRS team to customize the IRT to support the unique requirements of home infusions for patients too ill to seek treatment outside their home

Professional Experience (continued):

Agios Pharmaceuticals, Inc., Sr. Manager, Logistics—Technical Operations (Full-time)
Cambridge, MA
September 2015 – April 2017

Managed logistics globally for Agios Pharmaceuticals, Inc., a company of 300 employees and a first mover in using cellular metabolism as a platform for developing transformative medicines.

- Built the Chemistry, Manufacturing, and Controls (CMC) Logistics organization at Agios
- Managed the distribution of bulk drug substance, bulk drug product, reference standards, toxicology samples, and research compounds globally
- Created, reviewed, and approved shipping documents including FDA Automated Commercial Environment (ACE) compliant End Use Letters, United States Department of Agriculture (USDA) Statements, Toxic Substances Control Act (TSCA) Statements, and Prototype Exemption Letters
- Created and maintained an internal website to organize tracking data, metrics, Harmonized Tariff Schedule (HTS) Codes, FDA Product Codes, and valuations
- Created a 600+ line MS Project plan to outline the packaging strategy for our first commercial product launch which includes generating packaging specifications, creating batch records, developing internal SOPs, conducting child resistant and senior friendly package safety testing, initiating shipping validation testing, implementing serialization, and executing packaging validation
- Developed a strategy document that delineates, based on scientific evidence and process history, which product forms (API, SDI, bulk drug product, or finished goods) require shipping validation testing
- Authored shipping validation protocols according to American Society for Testing and Materials (ASTM) standards
- Oversaw child resistant and senior friendly package safety testing according to Consumer Product Safety Commission (CPSC) standards
- Audited research laboratories, API manufacturing facilities, warehouses, commercial packagers, commercial distributors, and trucking companies in Beijing, CN; Shanghai, CN; Allentown, PA; Rockford, IL; Frisco, TX; Louisville, KY; and Medina, OH

NPS Pharmaceuticals, Inc., Manager, Packaging—Global Technical Operations (Full-time)
Bedminster, NJ
June 2014 – September 2015

Managed packaging operations, artwork, components, and vendors for NPS Pharmaceuticals, Inc., a company of 300 employees and a pioneer in the rare disease biopharmaceutical space.

- Earned direct product launch experience by overseeing the secondary packaging of Natpara, a bioengineered treatment for a rare endocrine disorder known as Hypoparathyroidism
- Winner of the NPS Visionary Award. This award was earned for successfully managing domestic and international vendors in a 100% virtual model to rapidly launch Natpara after FDA approval
- Organized product launch activities among artwork agencies, thermoformed tray manufacturers, carton manufacturers, packaging insert printers, custom injection molders, and distributors
- Conducted a Failure Modes and Effects Analysis (FMEA) to assess the supply chain risk for the packaging, storage, and distribution of our Natpara launch

Professional Experience (continued):

- Coordinated Natpara packaging validation activities by contributing to the development of validation protocols, by troubleshooting irregularities, and by refining the process for commercial production
- Oversaw the creation, modification, and removal of specifications for secondary packaged components such as labels, cartons, trays, medical devices, and cartridge holders
- Developed batch records for UV printing labels on two types of medical devices, including an injector pen and a propitiatory 2-chamber cartridge mixing device
- Developed packaging batch records for 9 Natpara SKUs
- Prioritized product launch activities with the packaging of 4 existing SKUs for Gattex, the first prescription medicine for the long-term treatment of adults with Short Bowel Syndrome (SBS) who are dependent on parenteral support
- Participated in a corporate market cap expansion from $3.8 Billion to $5.2 Billion and an acquisition by Shire, a global innovator in specialty biopharmaceuticals

Merck, Global Clinical Supply Project Manager—Merck Research Laboratories (Full-time)
Summit, NJ
October 2006 – June 2014

Managed a global project team to design, develop, and implement a process for protecting temperature sensitive clinical supplies during storage and distribution

- Founded the Global Clinical Supply Packaging Technology organization at Merck
- Winner of the Merck Chairman's Award. The Merck Chairman's Award is the highest award granted at Merck and it is presented by the Merck Chairman and CEO. This award was earned for leading a global, cross-functional initiative to implement the return and re-use of environmentally friendly cold chain shipping containers that kept more than 3,000 tons of environmentally non-friendly material from landfills annually.
- Directed a cross-functional network of stakeholders and subject matter experts that included quality managers, research and development scientists, supply and demand project managers, engineers, logistics personnel, and clinical operations managers
- Oversaw the storage and distribution of temperature sensitive clinical supplies at Merck owned and at Merck contracted facilities in more than 70 countries
- Developed integrated global strategies and plans to assure the integrity of temperature sensitive clinical supplies
- Served as a contributing author for the ISPE Cold Chain Management Good Practice Guide and as an expert presenter at IQPCs Clinical Trial Supply USA conference
- Oversaw International Safe Transit Association (ISTA) shock and vibration testing for finished clinical kits
- Standardized scientific testing parameters across multiple developmental areas
- Developed a global website to share scientific and procedural knowledge across operations in more than 70 countries
- Pioneered the use of language independent animated videos to train stakeholders at more than 13,000 clinical sites
- Implemented the latest computer automated temperature monitoring technology
- Reduced distribution related temperature problems to less than 2% from more than 30%
- Oversaw a $6 million budget

Professional Experience (continued):

Schering-Plough, Global Clinical Supply Sr. Technical Trainer—Schering-Plough Research Institute (Full-time)
Kenilworth, NJ
March 2004 – October 2006

Managed training requirements, engineered processes, and oversaw compliance activities for organizations supporting Global Clinical Supply such as Engineering and Technical Services, Maintenance and Facility Services, and QC Microbiology.

- Directed a cross-functional team to engineer a new GMP facilities cleaning program in response to Consent Decree audit findings. This new program included a qualified disinfectant list, daily and monthly cleaning procedures, and a room cleaning schedule.
- Collaborated with a cross-functional team to re-design the Global Clinical Supply Equipment Cleaning Verification Program in response to Consent Decree audit findings. This re-design successfully resolved the audit findings, reduced unnecessary failures, and added predictability to the Equipment Cleaning Verification schedule.
- Created, in conjunction with a cross-functional team, a Job Rotations Program for Pharmaceutical Sciences. This program focused on talent recruitment, development, and retention and it was designed to facilitate career plans, improve communication between functional areas, and provide flexibility to meet changing business needs. The program won praise from Fred Hassan, Chairman and CEO of Schering-Plough.
- Managed training requirements for approximately 150 engineers, technicians, and scientists
- Developed, in electronic Learning Management Systems, learning plans, curricula, modules, and courses
- Partnered with a cross-functional team to create a new SOP development methodology. This methodology concentrated on usability by revising SOPs collectively rather than individually and by encouraging the use of tools such as photos and process maps.
- Authored dozens of SOPs such as Cleaning, Use, and Maintenance Logs, Good Documentation Practices (GDPs), the SOP on SOPs, and Stability Data Allocation.

Schering-Plough, Project Associate—New Jersey GMP Training Unit and Schering-Plough Research Institute (Consultant)
Kenilworth, NJ
February 2003 – December 2003

Collaborated with a project team to develop and implement a new site wide training program. Implementation of this training program was necessary to resolve Schering-Plough's Consent Decree.

- Developed and delivered a Train the Trainer program. This program implemented a new process designed to select, train, and certify employees as Qualified Trainers who would in turn be responsible for conducting training activities
- Led focused classroom sessions to instruct employees on the art of training
- Developed Standard Operating Procedures to integrate the training, qualification, and work assignment processes
- Led a team to assess the accuracy and completeness of historical training documentation

Professional Experience (continued):

Wyeth, Lead Investigator—R&D Quality Assurance Operations (Consultant)
Marietta, PA
September 2002 – December 2002

Collaborated with a cross-functional team to investigate manufacturing deviations that occurred during the production of clinical trial vaccines. Consent Decree resolution at this site was coupled to the assessment of these deviations.

- Interviewed a broad range of operations and scientific personnel to determine root cause
- Reviewed batch records, logs, procedures, and notebooks to provide supporting documentation
- Assessed the impact of administrating clinical trial vaccines without first resolving all manufacturing deviations

Aventis Pasteur, Industrial Operations Associate—Commercial Operations (Full-time)
Swiftwater, PA
January 2001 – January 2002

Supervised daily operations in a commercial sterile Filling and Packaging area.

- Coached, mentored, and developed team members
- Reviewed batch records, conducted line inspections, initiated change controls, performed incident investigations, and monitored processing parameters
- Led a team to replace critical processing equipment that was improperly installed and improperly validated
- Retained Ralph Stayer, former CEO of Johnsonville Foods, as an organization wide management and team development consultant

Certifications:

Certified in Production and Inventory Management (CPIM). Association for Supply Chain Management (ASCM), American Production and Inventory Control Society (APICS). Certification pending.

Certified Supply Chain Professional (CSCP). Association for Supply Chain Management (ASCM), American Production and Inventory Control Society (APICS). December 2017.

Certified Six Sigma Green Belt (CSSGB). American Society for Quality. June 2016

Project Management Professional (PMP). Project Management Institute. December 2014.

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through May 17, 2021

You have searched Finished drug products

Search Results: *'Amicus Therapeutics'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marke Date
Galafold	71904-100-01	123 mg/1	CAPSULE	ORAL	NDA208623	Amicus Therapeutics US, LLC	71904-100	migalastat hydrochloride	MIGALASTAT HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/10/2(

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Verified
M.H 5/26/2021

Date: 4/28/2021

To: Nevada Licensing or Registering Board or Agency:
(Name of State)

Name of Facility: Amicus Therapeutics US, LLC

Facility Address : 3675 Market Street Philadelphia, PA 19104

Facility License, Registration, or Record number : 95000010218

The information below is to be completed only by a Pennsylvania state Licensing or Registering Agency. Must have State seal to be valid.

pennsylvania
DEPARTMENT OF HEALTH

717-787-4779

Current Status: Active ☑ Yes ☐ No
Location: ☑ In state ☐ Out of State/Nonresident*
Type of Facility: Certificate of Record/Virtual manufacturer
Issue Date: 1/21/2021
Expiration Date: 2/28/2022

☑ The above facility is in good standing and has not had any formal disciplinary action under the above registration/license/record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program.

☐ The above facility has had any formal disciplinary action under the above registration/license record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program. Please explain:

Theresa [illegible], R.Ph.
Drug Program Staff- Name

Signature

Drug, Device, & Cosmetic Program (DDC Program)
Division of Home Health
Pennsylvania Department of Health

STATE SEAL:

*Interested parties are encouraged to verify status/standing with entity's home state or FDA if applicable.

Pennsylvania Department of Health

Drug, Device and Cosmetic Program
Public Lookup

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

- **Amicus Therapeutics US, LLC** 3675 Market Street; Philadelphia, PA 19104
  Certificate(s): **9500000218** issued: 1/21/2021 expires: 2/28/2022

Back to DD&C Home

Copyright © 2009-2018 Commonwealth of Pennsylvania. All Rights Reserved.

Assembly Version 4.0.18274.4
Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-33497

Amicus Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	71-0869350
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
3675 Market Street, Philadelphia, PA (Address of Principal Executive Offices)	19104 (Zip Code)

(215) 921-7600

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	FOLD	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Excbange Act. ☐

Indicate by check mark whether the registrant bas filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report .☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the 255,379,926 shares of voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as reported on The NASDAQ Global Market, as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2020) was $3,851,129,284. Shares of voting and non-voting stock held by executive officers, directors, and bolders of more than 10% of the outstanding stock have been excluded from this calculation because such persons or institutions may be deemed affiliates. This determination of affiliate

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the Proxy Statement for the registrant's 2021 Annual Meeting of Stockholders hich is to be filed subsequent to the date hereof are incorporated by reference into Part III of this Annual Report on Form 10-K.

Amicus Therapeutics

RECEIVED
MAY 25 2021
NEVADA STATE BOARD OF PHARMACY

May 18th, 2021

Via Fed Ex

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

To Whom It May Concern:

On behalf of Amicus Therapeutics US, LLC, attached is Amicus Therapeutics US, LLC's application for Virtual Manufacturer of a new facility location in Pennsylvania. On February 1st, 2021 Amicus Therapeutics US, Inc. change their name from Amicus Therapeutics US, Inc. to Amicus Therapeutics US, LLC. An ownership change did not take place, but only a name change as ownership structure and tax ID numbers have remained the same. Amicus also has opened a new location in Pennsylvania effective February 20th, 2021. Due to both changes we are submitting a new initial license application (please see their Pennsylvania license attached).

Amicus Therapeutics US, LLC. is a global biotechnology company at the forefront of advanced therapies to treat a range of devastating rare and orphan diseases. We have a robust development pipeline of treatments for a range of human genetic diseases. Our lead product, Galafold, is a personalized medicine to treat individuals with Fabry disease on the basis of their genetic diagnosis. Fabry disease is an X-linked disease caused by mutations in the GLA gene, which encodes the alpha-Gal A enzyme. These mutations can cause alpha-Gal A, to be either absent or deficient. When alpha-Gal A is absent or deficient the substrate, GL-3 and lyso-Gb 3 accumulate, leading to damage of cells within affected parts of the individual's body and causing the various pathologies seen in Fabry disease. Fabry disease leads to progressive, irreversible organ damage, typically involving the nervous, cardiac, and renal systems, as well as multiple other tissues. The symptoms can be severe, differ from patient to patient, and begin at an early age, resulting in significant clinical, humanistic, and healthcare costs. Fabry disease requires lifelong medical intervention to manage the complications of this devastating disease across multiple organ systems.

Amicus Therapeutics US, LLC, is a "Virtual Manufacturer" whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Amicus Therapeutics US, LLC's office. Amicus Therapeutics US, LLC's product is not a controlled substance.

I hope this narrative is helpful as you review Amicus Therapeutics US, LLC's application. If you have a question regarding this application, please contact me at 614-406-3129 or via email at theresa.carey@twolabs.com. Please also address all written communication to me. My address is 4005 S. Section Line Rd. Delaware, OH 43015.

Thank you in advance for your consideration.

Theresa Carey

TwoLabs PHARMA SERVICES

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: APL Sales I LLC

Physical Address: 100 Fifth Avenue, 7th Floor

City: Waltham State: MA Zip Code: 02451

Telephone Number: 617-977-5700 Fax Number: N/A

Toll Free Number: N/A

E-mail: david.acheson@apellis.com Website: N/A

Facility Manager: David Acheson

Professional qualifications and experience of facility manager:
See Attachment B

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☑
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment C
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

DocuSigned by:
David Acheson
135965FF3D3B480...
Original Signature of Person Authorized to Submit Application, no copies or stamps

David Acheson
Print Name of Authorized Person

1/21/2021
Date

Board Use Only Date Processed:_____ Amount: 500.00 CC

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: APL PRG I Corporation (wholly owned by Apellis Pharmaceuticals, Inc., a publicly traded company.)

Corporation Name: APL PRG I Corporation

Mailing Address: 100 Fifth Avenue, 7th Floor

City: Waltham State: MA Zip: 02451

Telephone: 617-977-5700 Fax: N/A

Contact Person: David Acheson

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Apellis Pharmaceuticals, Inc.

Date of Incorporation: 9/25/2009

Registration number issued: SEC #: 001-38276, DE file #: 4735405

Stock Exchange: Nasdaq

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment D

List of officers and directors. See Attachment E

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: APL PRG I Corporation (wholly owned by Apellis Pharmaceuticals, Inc., a publicly traded company.)

Mailing Address: 100 Fifth Avenue, 7th Floor

City: Waltham State: MA Zip: 02451

Telephone: 617-977-5700 Fax: N/A

Contact Person: David Acheson

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?
N/A - no shares issued. The LLC is owned by:

a) APL PRG I Corporation — 100 Fifth Avenue, 7th Floor, Waltham, MA 02451
Name — Business Address

b) _____
Name — Business Address

c) _____
Name — Business Address

d) _____
Name — Business Address

2) Provide the number of shares issued by the corporation. N/A - LLC, no shares issued

3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment D

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment E

Attachment A

Regarding the Resident State License and Verification

Enclosed is a copy of the resident state license. Verification of licensure is currently pending receipt from the resident state licensing agency, the Massachusetts Department of Public Health. Once received, the verification will be provided to your office to accompany this pending application.

The Commonwealth of Massachusetts
DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000098	01/04/2021	01/04/2022	Virtual Drug Distributors

ISSUED TO

APL SALES I LLC
100 FIFTH AVENUE
7TH FLOOR
WALTHAM, MA 02451
ATTN: DAVID ACHESON SVP, NORTH AMERICA

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

NEW

842425

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000098	01/04/2021	01/04/2022	Virtual Drug Distributors

ISSUED TO

APL SALES I LLC
100 FIFTH AVENUE
7TH FLOOR
WALTHAM, MA 02451
ATTN: DAVID ACHESON SVP, NORTH AMERICA

NEW

The Commonwealth of Massachusetts
DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000098	01/04/2021	01/04/2022	Virtual Drug Distributors

ISSUED TO APL SALES I LLC
100 FIFTH AVENUE
7TH FLOOR
WALTHAM, MA 02451
ATTN: DAVID ACHESON SVP, NORTH AMERICA

COMMISSIONER OF PUBLIC HEALTH

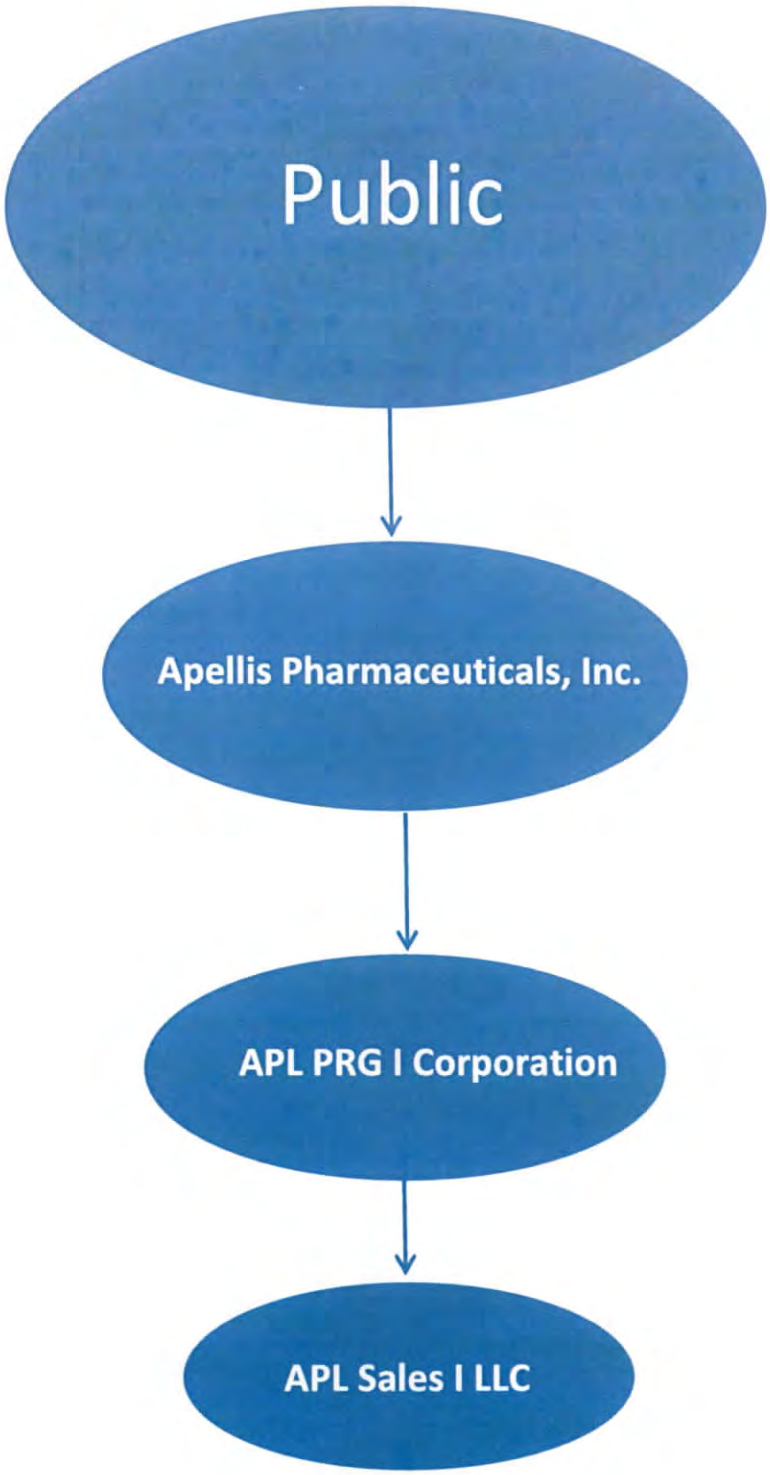
FILE COPY

NEW

842425

Attachment

Ownership Chart



Attachment B

Facility Manager's Resume

Maria Herrera

From: Lam, Maggie P. <lam@porziols.com>
Sent: Thursday, April 1, 2021 10:00 AM
To: Maria Herrera
Subject: FW: Nevada wholesaler Application- APL Sales I LLC

Maria,

As a follow-up regarding APL Sales I LLC's pending application, note that the DR, David Acheson, is technically employed fulltime by the ultimate parent company (grandparent co.), Apellis Pharmaceuticals.

David, however, will only be the DR for the applicant, APL Sales I LLC, and meets all other requirements listed.

Kindly confirm if there is any additional information required.

Thanks for your help with this application.

Regards,

Maggie

From: Maria Herrera
Sent: Thursday, January 28, 2021 11:22 AM
To: 'david.acheson@apellis.com' <david.acheson@apellis.com>
Cc: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: Nevada wholesaler Application- APL Sales I LLC

The Nevada State Board of Pharmacy received an Out-of-State Wholesaler application from APL Sales I LLC. Based on the information stated on Attachment F, the company appears to be wholly owned by a publicly traded company. If this is correct please provide the following;

- Organization chart attached
- Update Certificate of Good Standing attached
- Copy of parent company 10k report The entire report is over 300 pages. Attached are the first 15 pages. You may view the entire report here: https://investors.apellis.com/financial-information/sec-filings?field_nir_sec_form_group_target_id%5B%5D=471&field_nir_sec_date_filed_value=#views-exposed-form-widget-sec-filings-table
- Please confirm that facility manager, David Acheson is employed full time by APL Sales. Pursuant to NAC 639.5935 (4)(b)(c) – checking on this

NAC 639.5935Representative of wholesaler: General requirements; exceptions; approval; enforcement. (NRS 639.070, 639.100)

1. Except as otherwise provided in this subsection, an applicant for a license, or a licensee with a license, to operate as a wholesaler shall designate at least one natural person to serve as the representative of the wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a wholesaler

David Acheson

Apellis Pharmaceuticals, Inc.

Senior Vice President, Head of US

Generated on July 1, 2019

Personal

David Acheson

Senior Vice President & General Manager, US Operations
Circassia Pharmaceuticals plc

Education & Certifications

Bachelor, Bachelor of Science, AgriBusiness 1995
University of Nebraska–Lincoln *Verified*

Career Summary

2019 - Current	**Circassia Pharmaceuticals plc** Senior Vice President & General Manager, US Operations
2016 - 2018	**Circassia Pharmaceuticals** Senior Vice President, US Commercial
2013 - 2015	**BioDelivery Sciences International, Inc.** Vice President, Sales and Managed Markets
2013 - 2013	**CSL Behring LLC** National Director, Sales, Immunology & Pulmonary
2011 - 2013	**Pacira Pharmaceuticals Inc.** National Sales Director/Project Lead, Hospital Specialty Surgery Team (Quintiles)
2003 - 2011	**Meda Pharmaceuticals Inc.**
2008 - 2011	National Sales Director
2005 - 2007	Regional Director, Northeast Region
2003 - 2005	District Sales Manager
2000 - 2003	**Roche Pharmaceuticals** Hospital Division Sales Manager
1995 - 2000	**American Cyanamid Co (Now Cytec Industries Inc.)** District Sales Manager

Candidate Provided Information

[redacted] Roslin Way, Holly Springs, NC 27540 • [redacted]

David L. Acheson

Experienced Executive Leader

Progressive leader with consistent record of top performance. Career reputation of innovative strategic thinking that establishes high standards for organizations. History of meeting and exceeding commercial goals and sales revenues while managing P&L. Extensive experience in building and leading organizations from start-up phase to full commercial execution.

- Managed Markets Strategy & Execution
- Full Commercial Team Start-Up/Leadership
- Matrix/Cross-Functional Leadership
- Well versed in Hospital/Specialty Sales
- Multiple Specialty Markets/REMS
- Trade/Channel Set-up & Pull Through/Relations
- Sales Force Deployment & Scaling
- Personnel Coaching & Development
- Buy-And-Bill Contracting/Negotiations/Pull Through
- Specialty Pharmacy Partnerships/Rare Disease Experience

Professional Experience

1/17/16 – Present **Circassia Pharmaceuticals** Raleigh, NC

Senior Vice President & General Manager, US Operations (12/5/16 – Present)

Core products: NIOX (Device that measures FeNO for airway inflammation) – focused on Allergy/Asthma/COPD patients with Allergists, Pulmonologists, aligned Primary Care offices ; Tudorza Pressair (aclidinium bromate) focused on treatment of COPD within Pulmonology/PC
Reports: Entire Commercial Organization in the US and Globally based for Marketing, Commercial Operations, Training; Matrix reporting with all other departments (HR, Regulatory, Quality, Compliance, IT, Logistics, Finance); Commercial organization of 205 and all other groups total 56 corporate based employees

Key Responsibilities:

- Fully responsible for all US operations and full P&L; Member of Global Senior Management Team (SMT)
- Leading revenue generation of $150MM gross sales across two brands (NIOX – Device) (Tudorza – COPD anticholinergic)
- Build and implement entire US sales and commercial strategy for current and future portfolio
- Lead and oversee development of full global Marketing and Commercial Operations teams, strategies and operational efforts
- Implement the first ever Market Access strategy with Medical Directors of key payers for NIOX device and testing; results in less than 12 months of ~20% additional US lives covered (~50MM lives); additional ~69MM lives reviewed and covered
- Fully accountable to managing collaboration contract between AstraZeneca and Circassia on a global basis, as well as bringing in currently marketed COPD products; full planning and preparation for launch of acquired products for 2019

Outcomes & Performance:

- NIOX revenue growth 70% from 2016 to close of year 2018
- New NIOX device sales up 40% 2016 to close of 2018
- Signed 84 new US key account contracts in less than 12 months; pull through on-going
- Increased payer coverage by >30MM lives in 2017; an additional 69MM lives gained 2018
- Facilitated commercial portion of unique business development deal with AstraZeneca for Tudorza Pressair
- Completely re-organized and rebuilt US commercial organization, closing Chicago facility and re-hiring entire team in Raleigh; full sales force expansion from 100 to 200 territories completed during the same time period
- Fully integrated Tudorza Pressair into the organization, finishing the 2017 achieving $66MM in net sales, stopped decline of product that formerly was not prioritized for promotion by AstraZeneca, re-organized full commercial approach for 2019 including gross-to-net management of large key payer rebates with shift to lower negotiated rebates for July 1, 2019 & January 1, 2020 initiation of new contract dates that will result in ~$25-35MM in gained net revenues for 2020
- Fully re-organized the US organization in preparation for new product PDUFA in COPD, and addition of new device nitric oxide use in the hospital setting; COPD launch set for Q3/Q4 2019, new device launch set for 1H 2020

Vice President of Sales (1/17/16 – 12/5/16) – Chicago IL/Raleigh NC

Core products: NIOX (Device that measures FeNO for airway inflammation) – focused on Allergy/Asthma/COPD patients with Allergists and Pulmonologists
Reports: 5 Regional Sales Managers and 50 Territory Business Managers; expanded to 100 TBMs, 10 RSMs, 2 Area Sales Directors, a full Key Accounts team (1 Director and 5 Key Account Managers) and a Market Access team (1 Director and 5 Regional Account Managers)

Key Responsibilities:

- Fully responsible for all sales, Key Accounts, Market Access/Payer policy work for the US business within a global organization; built Key Accounts and Market Access teams from scratch, expanded field team from 50 to 100 territories
- Build and implement entire US sales and commercial strategy for NIOX post Circassia acquisition of Aerocrine
- Implement the first ever Market Access strategy with Medical Directors of key payers
- Fully developed a Key Opinion Leader plan and strategy for the organization with Allergy and Pulmonology specialties
- Fully responsible for leadership of multi-disciplinary teams and direct reports

Candidate Provided Information (Cont.)

12/2013 - 8/2015 **BioDelivery Sciences** Raleigh, NC

Vice President, Sales & Managed Markets

Core products: BUNAVAIL (buprenorphine/naloxone) - $28MM budget/P&L accountability - Estimated 2015 Sales of **$20MM - $28MM**
Reports: 5 Regional Sales Managers & 57 Sales Reps, 1 Director of Managed Markets and 8 NAMs, 1 Director of Trade, 1 Director of Training, 1 Director of Operations, 1 CSO based National Sales Director/Project Lead

Key Responsibilities:

- Build and implement entire commercial strategy for the launch of BUNAVAIL in the opioid dependence market
- Lead the development of complete market access strategy and execution plan for product placement on key MCO formularies, including direct work with top PBMs, top 48 targeted payer accounts, top 17 state Medicaid plans, and top 25 Managed Medicaid plans that make up over 80% of the total prescriptions in the buprenorphine/naloxone market
- Fully responsible for leadership of multi-disciplinary teams and direct reports in the full build of the following:
  - Field sales team structure and deployment - both contract sales & manufacturer owned (Sales)
  - Commercial organization operational support/structure (Operations)
  - Trade/pharmacy access strategy through key wholesalers, retail pharmacies, specialty pharmacies (Trade)
  - Logistics/distribution plan including fully operational 3PL (third party logistics) and back office financial support
  - Corporate and sales training and development program and structure (Training & Development)

Outcomes & Performance:

- Launched BUNAVAIL Q4 2014 under limited supply, yet stocked **5,500 stores** in strategic launch markets and 110 wholesaler DSAs
- Gained access prior to launch in 3rd tier position with payers to **165MM covered lives** in key commercial PBMs and plans across targeted markets (MSAs); negotiated contracts to gain 2nd & 3rd tier open access to **185MM (80%)** lives by August, 2015
- Negotiated top two targeted payers in the U.S. in opioid dependency market (TennCare, BCBS TN) to have BUNAVAIL as preferred product, exclusive with TennCare and 2nd tier preferred with BCBS TN within 9 months of product launch
- Built and executed a Medicaid & Veterans Affairs plan, gaining access to **11 of 17 targeted state Medicaid formularies** and secured a VA market share performance contract for **$14MM in annual revenue**
- Q4 2014/Q1 2015 sales resulted in **$2.1MM** followed by **$3MM (50% growth)** in Q2, **$5.1MM in Q3 (65% growth)** on track for **$7.1MM in Q4 (40% growth)**
- Designed a unique "guaranteed stocking program" with Walgreens for key launch - aligned to managed care wins and sales force presence - Q2 program pilot successful in the states of MA and TN, negotiated with Walgreens to expand to other targeted markets in Q4

3/2013 - 12/2013 **CSL Behring** King of Prussia, PA

National Sales Director, Immunology & Pulmonary Specialty Teams

Core products: HIZENTRA - $300MM; PRIVIGEN - $140MM; BERINERT - $85MM; ZEMAIRA - $109MM
Reports: **Immunology Team** - 5 Regional Sales Managers, 43 Account Managers
Pulmonary Team - 4 Regional Sales Managers, 31 Account Managers, 4 Support Specialists

- Led ***two separate nationally based sales teams*** with focus in the immunoglobulin, hereditary angioedema, alpha-1 antitrypsin deficiency
- Held a leadership position within the global Specialty Business Team, responsible for full management decisions and pull through of the specialty product portfolio for CSL
- Extensive work with specialty pharmacies, distributors, payers, IDNs, and GPOs including contract pull through
- Designed and executed field sales force development and training program - program new to CSL
- Built proposal for ***Pulmonary team expansion*** for improved market place penetration - plan approved by executive leadership and expansion completed in Fall of 2013
- ***NOTE:*** *Left due to being recruited by senior leadership at BioDelivery Sciences for full commercial build*

9/2011-2/2013 **Pacira Pharmaceuticals (Quintiles, Inc)** Parsippany, NJ

National Sales Director/Project Lead, Hospital Specialty Surgery Team - Quintiles

Core products: EXPAREL - $14MM budget/P&L accountability *Reports:* 7 Regional Directors; 63 Hospital Surgery Specialists

- Built from start-up operation a new hospital based specialty team focused on the positioning and promotion of EXPAREL for infiltration into the surgical site to produce postsurgical analgesia - target audiences of **Surgeons, Anesthesiologist, OR Staff, PACU, Pharmacy**
- Navigated pre-launch manufacturing challenges, delaying launch by a full quarter in Q1 2012 while realizing less than **2% turn over**
- Designed pre-launch execution plan to include P&T/formulary committee work
  - Despite product delay had **123** top tier targeted accounts set P&T review dates for late Q1/early Q2
- Led sales organization in first quarter of promotion and pull through (Q2 2012) of **$2.3MM in revenue**, exceeding internal and investor expectations followed by a **$4.6MM revenue** second quarter (Q3 2012) and **$8MM in revenue** for the third quarter of sales (Q4 2012)
- Pulled product through **834 accounts** with a re-order rate of **55%** in total; **68% re-order rate realized in hospital accounts**
- Fully designed and implemented internal tele-sales group (Virtual Sales Reps) to create frequency of message with select plastic surgery targets; initial investment of $60K generated **$190K documented sales in first quarter of execution resulting in expanded program**
- Led the cross-functional and dual company (Quintiles/Pacira) integration project

Candidate Provided Information (Cont.)

1/2004 - 9/2011 **Meda Pharmaceuticals** Somerset, NJ

National Sales Director, Oncology Supportive Care Team (4/2009 - 9/2011)

Core products: ONSOLIS, CESAMET, MUSE *Reports:* 5 Regional Sales Managers; 43 Specialty Representatives

- Developed team from start-up operations; designed Sales, Operations, and Training
- Member of the Commercial Executive Team and New Business Development Team
- **Select Achievements:**
  - Pioneered first ever Risk Evaluation & Mitigation Strategy (REMS) program for fentanyl/opioid market
  - Launched Cesamet (nabilone), sales resulted **in 219% growth** from prior sales efforts with previous company
  - Led sales and commercial integration of Vivus sales organization specific to urology specialty
    - Acquisition of Vivus (MUSE) urology organization complete and Nov 2010, integration Jan 2011
    - MUSE sales posted **122% revenue** goal post acquisition
  - Appointed by President of Meda US to lead a newly established **Integration Steering Committee**

National Sales Director, Respiratory Team (1/2008 - 4/2009)

Core Products: ASTELIN, OPTIVAR, ASTEPRO, SOMA 250 *Reports:* 8 Area Sales Managers; 88 Respiratory Specialty Reps

Select Achievements:

- National team led product conversion rate in **excess of 50% vs. projected 35%** with key targeted accounts
- Accountable to all KOL development, physician peer-peer exchanges/programming, and focused market development among specialists
  - Led collaborative efforts with marketing, compliance, legal and regulatory departments to redesign speakers bureau internal process to align with new government compliance and requirements
  - Results of new process and standards was **100% execution** to new requirements and audits

Additional Positions Held at Meda Pharmaceuticals:

- Regional Director, Northeast Region, Somerset, NJ (9/2005 - 1/2008) *Reports:* - **President's Club Winner**
  - ***Reports:*** 9 District Sales Managers, 120 Sales Reps; led 33% regional field expansion in 2005
  - Moved region performance from ***4 of 4*** in rankings to ***1 of 4*** in rankings in less than 2 years
- District Sales Manager, Midwest, Kansas City, KS (1/2004 - 9/2005) - **President's Club Winner**
  - Moved District performance from ***23 of 26*** in rankings to ***2 of 26*** in less than 18 months

Additional Professional Experience

- **Roche Pharmaceuticals**, IA and KS locations (4/2000 - 1/2004)
  - Hospital Division Sales Manager, Kansas City, KS (2001-2004)
  - Medical Center Rep, Iowa City, IA (2001)
  - Professional Products Rep, Iowa City, IA (2000-2001)
- **American Cyanamid Company**, ND, IA, and NE locations
  - District Sales Manager, Fargo, ND (1999-2000) - **Circle of Excellence Winner**
  - Market Development Supervisor/RBM, Des Moines, IA (1997-1999)
  - Territory Sales Rep, Columbus, NE (1995-1997) - **President's Club Winner**

Education

1990 - 1995 **University of Nebraska - Lincoln** Agribusiness (B.S.)

Engagement Team

Oliver Schiltz

Office: +41 44 4881372
Mobile: [redacted]
Email: oschiltz@heidrick.com

Ina Sood

Office: +1 202 974-6067
Mobile: [redacted]
Email: isood@heidrick.com

Brendan O'Brien

Mobile: [redacted]
Email: bobrien@heidrick.com

Meredith Barnes

Office: +1 202 974 6079
Email: mbarnes@heidrick.com

Linnea Kennedy

Office: +1 (202) 331-4929
Mobile: [redacted]
Email: lkennedy@heidrick.com

Heidrick & Struggles serves the executive leadership needs of the world's top organizations as a trusted advisor for leadership consulting, culture shaping and senior-level executive search services. Our data driven solutions empower senior executives and boards of directors to transform their organizations by leveraging top talent and accelerating performance across all layers of the business.

Attachment C

Nature of Business

APL Sale I LLC (APL) is a virtual wholesale distributor of non-controlled prescription drugs. APL is owned by APL PRG I Corporation which is owned by Apellis Pharmaceuticals, Inc., a publicly traded company. APL will sell a product labeled by Apellis Pharmaceuticals, Inc. The first product to be sold by APL will be pegcetacoplan. The product is used to treat a rare blood disorder. APL will not handle any product at its business office. APL will use a third party to ship the product. Below is the contact information for the party logistics provider.

Third Party Logistics Provider:

Cardinal Health
15 Ingram Blvd.
La Vergne, TN 37086-3630

Attachment D

LLC Officer Information

Apellis Sales I LLC
100 Fifth Avenue, 7th Floor
Waltham, MA 02451

Esther Langer
Head Patient Services, Trade & Distribution

Becky Bailey Bristol
VP, North America Sales and Marketing

David Acheson
SVP North America

Attachment E

Delaware Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "APL SALES I LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "APL SALES I LLC" WAS FORMED ON THE SIXTH DAY OF NOVEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

3893472 8300

SR# 20208578597

Authentication: 204249305

Date: 12-07-20

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "APL SALES I LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF DECEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "APL SALES I LLC" WAS FORMED ON THE SIXTH DAY OF NOVEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

3893472 8300

SR# 20208578597

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204249305

Date: 12-07-20

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM_____ TO _____

Commission File Number 001-38276

APELLIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	27-1537290
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Fifth Avenue Waltham, MA (Address of principal executive offices)	02451 (Zip Code)

Registrant's telephone number, including area code: (617) 977-5700

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	APLS	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2020, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Stock Market on such date, was $1,953,553,262. The number of shares of the registrant's common stock, par value $0.0001 per share outstanding as of February 22, 2021 was 80,375,365.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2021 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2020. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	40
Item 1B.	Unresolved Staff Comments	83
Item 2.	Properties	83
Item 3.	Legal Proceedings	83
Item 4.	Mine Safety Disclosures	84
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	85
Item 6.	Selected Financial Data	87
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	89
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	104
Item 8.	Financial Statements and Supplementary Data	104
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	134
Item 9A.	Controls and Procedures	134
Item 9B.	Other Information	136
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	137
Item 11.	Executive Compensation	137
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	137
Item 13.	Certain Relationships and Related Transactions, and Director Independence	137
Item 14.	Principal Accountant Fees and Services	137
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	138

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans with respect to our ongoing and planned clinical trials for our product candidates, whether conducted by us or Swedish Orphan Biovitrum AB (Publ) or by any future collaborators, including the timing of dosing of patients, enrollment and completion of these trials and of the anticipated results from these trials;
- our plans to develop our current and future product candidates for any additional indications;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our plans to initiate clinical trials of our current and future product candidates;
- the potential clinical benefits and attributes of our current and future product candidates we may develop and the inhibition of C3;
- our plans to research and develop any current and future product candidates we may develop;
- our current and any future collaborations for the development and commercialization of our current and future product candidates;
- the potential benefits of any collaboration;
- the rate and degree of market acceptance and clinical utility of any products for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional products or product candidates with significant commercial potential;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry;
- the impact of the COVID-19 pandemic on our clinical trials, business and operations; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report on Form 10-K and the documents that we have filed or incorporated by reference as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. We believe that the information from these industry publications, surveys and studies is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. The Apellis and Apellis Assist names and logos are our trademarks, trade names and service marks.

The other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

RISK FACTOR SUMMARY

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in the "Risk Factors" section of this Annual Report on Form 10-K. Our principal risks include the following:

- We have incurred significant losses since inception, expect to incur significant and increasing losses for at least the next several years, and may never achieve or maintain profitability. Our net losses were $344.9 million, $304.7 million and $127.5 million for the years ended December 31, 2020, 2019 and 2018, respectively.

- We have not yet successfully obtained marketing approvals nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects. We will need to transition from a company with a development focus to a company capable of supporting commercial activities.

- We will need substantial additional funding, to allow us to support both the systemic and opbthalmological pegcetacoplan programs through commercial launch, and if we are unable to raise capital wben needed, we could be forced to delay, reduce or eliminate certain product development programs or commercialization efforts. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements at least into the second balf of 2022.

- If we receive regulatory approval for the use of pegcetacoplan as a treatment for PNH or if our agreement with SFJ Pharmaceuticals Group, or SFJ, is terminated prior to receiving such approval in specified circumstances, we will be required to make substantial payments to SFJ pursuant to our development funding agreement. If we do not have sufficient funding or cash flow from our business to meet our payment obligations under the development funding agreement, SFJ could exercise its remedies as a holder of a first priority security interest in our assets and our business could be materially harmed.

- We are dependent on the successful development and commercialization of pegcetacoplan. If we are unable to develop, obtain marketing approval for or successfully commercialize pegcetacoplan or if we experience significant delays in doing so, our business could be harmed.

- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaborators such as Swedish Orphan Biovitrum AB (Publ), or Sobi, from obtaining approvals for the commercialization of pegcetacoplan or any of our product candidates that we develop. As a result, we cannot predict when or if, and in which territories, we, or our collaborators, will obtain marketing approval to commercialize pegcetacoplan or any other product candidate that we develop.

- The COVID-19 pandemic may affect our ability to conduct our ongoing clinical trials, delay the initiation of planned and future clinical trials, disrupt regulatory activities, or have other adverse effects on our business and operations. In addition, the COVID-19 pandemic may adversely impact economies worldwide, which could result in adverse effects on our business and operations and ability to raise capital.

- There are no approved therapies that act by inhibiting C3 and only two approved therapies in our target indications that act by inhibiting the complement system. We may not be able to successfully develop and commercialize pegcetacoplan or other product candidates.

- If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other regulators, we may incur additional costs or experience delays in completing, or ultimately be able to complete, the development and commercialization of these product candidates.

- We rely on third parties to conduct our clinical trials and to manufacture and distribute our product candidates for our clinical trials. We contract with third parties for the manufacture, storage and distribution of our product candidates for clinical trials as well as in connection with our commercialization efforts. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. If these third parties do not perform satisfactorily, our development or commercialization efforts could be delayed or impaired.

- Our prospects for the development and commercialization of our product candidates will depend in significant part on the success of our collaboration with Sobi for the global co-development and commercialization of systemic pegcetacoplan outside of the United States. Our ability to generate revenues from this collaboration will depend on Sobi.

- If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business, including our patent license agreements with the University of Pennsylvania under wbich we license patents with claim that recite a class of compounds generically covering our lead product candidates, pegcetacoplan and APL-9, and that specifically recite the active component.

Item 1. Business.

We are a clinical-stage biopharmaceutical company focused on the development of novel therapeutic compounds to treat disease through the inhibition of the complement system, which is an integral component of the immune system, at the level of C3, the central protein in the complement cascade. We believe that this approach can result in broad inhibition of the principal pathways of the complement system and has the potential to effectively control a broad array of complement-dependent autoimmune and inflammatory diseases.

We have the most advanced clinical programs targeting C3 with Phase 3 clinical trials of our lead product candidate, pegcetacoplan, in multiple indications. We believe that pegcetacoplan has the potential to be a best-in-class treatment that may address the limitations of existing treatment options or provide a treatment option where there currently is none. Pegcetacoplan has already shown activity that we believe is clinically meaningful in clinical trials for several distinct medical conditions, including geographic atrophy in age-related macular degeneration, or GA; paroxysmal nocturnal hemoglobinuria, or PNH; cold agglutinin disease, or CAD; and C3 glomerulopathy, or C3G. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration and plan to conduct clinical trials of these compounds in additional complement-dependent indications.

In October 2020, we entered into a collaboration and license agreement, or the collaboration agreement, with Sobi. Under the collaboration agreement, we agreed to co-develop pegcetacoplan for systemic indications, including PNH, CAD and hematopoietic stem cell transplantation-associated thrombotic microangiopathy, or HSCT-TMA, in hematology; C3G and immune complex membranoproliferative glomerulonephritis, or IC-MPGN, in nephrology; and amyotrophic lateral sclerosis, or ALS, in neurology. Sobi has exclusive ex-U.S. commercialization rights for systemic pegcetacoplan. We retain commercialization rights for systemic pegcetacoplan in the United States and worldwide commercial rights for ophthalmological pegcetacoplan, which includes our GA program in addition to worldwide commercialization rights for APL-9 and other product candidates targeting C3.

Ophthalmological pegcetacoplan

GA. We initiated a Phase 3 clinical program consisting of two Phase 3 clinical trials evaluating ophthalmological administration of pegcetacoplan in patients with GA in September 2018. We refer to these trials as the DERBY and OAKS trials. Both trials are fully enrolled and we expect to announce top-line data from these trials in the third quarter of 2021.

In our Phase 2 clinical trial of pegcetacoplan in patients with GA, treatment with pegcetacoplan resulted in a significant reduction in the rate of GA lesion growth over 12 months.

Additionally, data released in October 2020 from a post hoc analysis of seven patients in our Phase 1b trial of pegcetacoplan in patients with advanced GA and low vision demonstrated a trend in reduced lesion growth in eyes treated with pegcetacoplan versus untreated fellow eyes after 18 months of treatment.

Systemic pegcetacoplan

We are developing pegcetacoplan with Sobi for systemic administration in several indications, including PNH, C3G, IC-MPGN, ALS, CAD and HSCT-TMA.

PNH. In June 2018, we initiated a Phase 3 clinical trial evaluating pegcetacoplan in 80 patients with PNH who exhibited signs of moderate to severe anemia, specifically with an inclusion criterion of hemoglobin level of less than 10.5 g/dL, while being treated with eculizumab, an approved therapy for PNH that is marketed as Soliris. We refer to this trial as the PEGASUS trial.

In January 2020, we announced top-line data from the PEGASUS trial that showed that pegcetacoplan met the trial's primary efficacy endpoint, demonstrating superiority to eculizumab, with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 ($p < 0.0001$), and promising results in key secondary endpoints. Additional data from the PEGASUS trial presented in June 2020 and December 2020 demonstrated increased hemoglobin levels, reduced transfusion requirements and improved key markers of hemolysis across the patient population, both in patients with high transfusion requirements and in patients with low or no transfusion requirements, which improvements were sustained through 48 weeks of treatment. In the PEGASUS trial, the safety profile of pegcetacoplan was comparable to that of eculizumab.

In September 2019, we initiated a second Phase 3 clinical trial in patients with PNH who have not been treated with eculizumab within three months before entering the trial. We refer to this trial as the PRINCE trial. The PRINCE trial is fully enrolled and we intend to present top-line data in the second quarter of 2021.

We submitted a new drug application, or NDA, to the FDA and a marketing authorization application, or MAA, to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the Prescription Drug User Fee Act, or PDUFA, target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021.

C3G/IC-MPGN. We have initiated and will continue to lead our registrational program in C3G / IC-MPGN. In October 2020, we reported data from the Phase 2 DISCOVERY trial in five C3G patients treated with pegcetacoplan for 48 weeks. We initiated a Phase 2 randomized, controlled trial in up to 12 patients with post-kidney transplant recurrence of C3G or IC-MPGN, in October 2020 and we expect to dose the first patient in this trial in the first half of 2021. We refer to this trial as the NOBLE trial. We also plan to begin a Phase 3 clinical trial in patients with native kidney or post-transplant recurrence of C3G or IC-MPGN, having reduction of proteinuria as its primary endpoint, in the second half of 2021.

ALS. We have initiated a randomized, placebo-controlled Phase 2 clinical trial of pegcetacoplan in approximately 200 adults with sporadic ALS. We refer to this trial as the MERIDIAN trial. We treated the first patient in the MERIDIAN trial in November 2020 and expect to complete enrollment for the MERIDIAN trial in the second half of 2021.

CAD and HSCT-TMA. Under our collaboration, Sobi will lead development activities for CAD and HSCT-TMA with a Phase 3 clinical trial in CAD and a Phase 2 clinical trial in HSCT-TMA, both planned to begin in 2021. In our Phase 2 clinical trial of pegcetacoplan in patients with CAD, patients achieved increased hemoglobin levels, reduced reticulocytes and bilirubin levels, and reduced LDH levels compared to baseline.

Pipeline

We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration. We plan to conduct clinical trials of these compounds in additional complement-dependent indications.

APL-9 is a C3 modulator designed to be intravenously administered for acute use. In May 2020 we initiated a Phase 1/2 randomized, placebo-controlled clinical trial of APL-9 in 66 patients with respiratory failure including acute respiratory distress syndrome, or ARDS, secondary to COVID-19. We expect to report results from this trial in the second quarter of 2021.

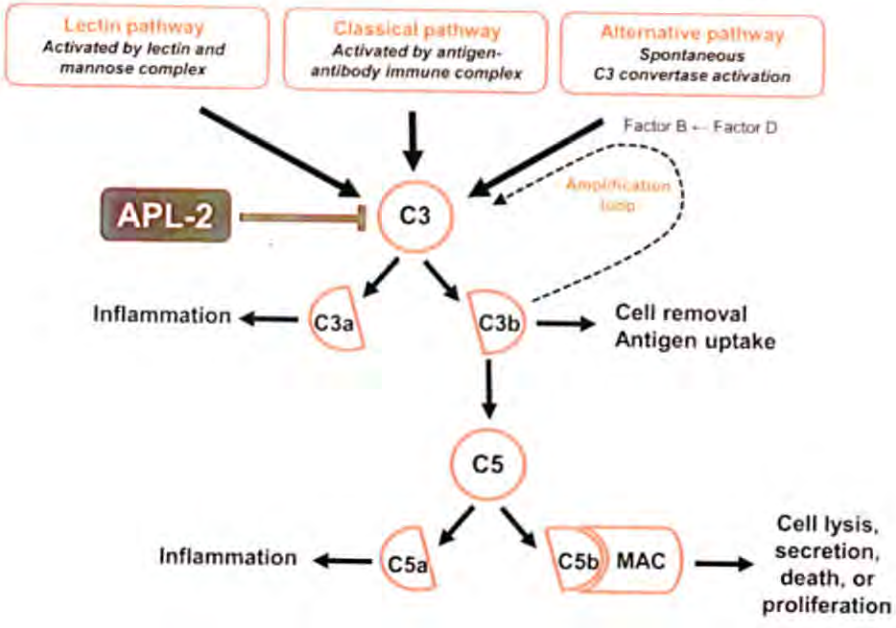
We are also developing APL-9 for the prevention of complement immune system activation coincident with adeno-associated virus, or AAV, vector administration for gene therapies and other indications.

We plan to advance three new product candidates into clinical development by the end of 2022.

Our Approach

The complement system plays a pivotal role in both innate and adaptive immune systems. Complement proteins are produced primarily by the liver and circulate in the blood and through the body's tissues. The complement system may be activated through three principal pathways, known as the classical, lectin and alternative pathways, each of which requires the C3 protein to enable three principal immune responses: opsonization, inflammation and formation of the membrane attack complex, or MAC. When C3 is activated, C3 fragments, such as C3b, tag cell surfaces in a process called opsonization, which marks the cells for removal from tissues or the bloodstream. Two other fragments, C3a and C5a, are released, contributing to inflammation in the surrounding tissues. Further complement activation causes membrane attack complex formation on cell surfaces, piercing holes and causing cells to lyse, or rupture, and others to depolarize or lose membrane potential.

The following figure depicts the complement system, its three principal activation pathways and its principal effects:



Under conditions of excessive or uncontrolled activation, the complement system is believed to play a key role in the incidence and progression of several autoimmune and inflammatory diseases. In these diseases, the complement system acts directly through tissue destruction by the membrane attack complex and indirectly by signaling other elements of the immune system to inappropriately target otherwise healthy tissues. Because the contribution of complement activation to the development and progression of these diseases is not fully understood, it has been difficult to develop therapeutics that ameliorate the conditions contributing to these diseases by targeting only one of the complement activation pathways.

Complement activation and its effects can be inhibited in multiple ways. By targeting complement proteins upstream of C3, one of the three principal activation pathways can be inhibited. For example, inhibition of factor B or factor D results in inhibition of the alternative pathway, but not the classical or lectin pathways. The complement system can also be inhibited by targeting complement proteins downstream of C3, which results in limited inhibition of complement effects. For example, inhibition of C5 leads to inhibition of the formation of the membrane attack complex and C5a-mediated inflammation but does not affect opsonization or C3a-mediated inflammation.

We have designed pegcetacoplan to target complement proteins centrally at the level of C3. We believe that this approach can result in broad inhibition of the complement pathways and has the potential to effectively control complement-dependent diseases. We believe that pegcetacoplan has the potential to be a best-in-class treatment and may address the limitations of existing treatment options or provide a treatment option where there is none.

Our Strategy

We aim to become a leading biopharmaceutical company focused on the discovery, development and commercialization of therapeutics to treat autoimmune and inflammatory diseases through complement inhibition. We hold commercialization rights for systemic pegcetacoplan in the United States and worldwide commercialization rights to ophthalmological pegcetacoplan, which includes our GA program, in addition to worldwide commercialization rights for APL-9 and other novel compounds targeting C3. To achieve our goals, we are pursuing the following strategies:

- ***Complete Phase 3 clinical development and prepare for regulatory submission of pegcetacoplan in GA***. We are developing pegcetacoplan as monotherapy for GA, administered by intravitreal injections. We expect to announce data from the DERBY and OAKS trials in the third quarter of 2021 and to prepare submissions to regulatory authorities for marketing approval of pegcetacoplan as a treatment of geographic atrophy.
- ***Prepare for commercialization of pegcetacoplan in PNH.*** We are developing pegcetacoplan as monotherapy for patients with PNH, administered by subcutaneous injection, and are preparing to commercialize systemic pegcetacoplan in the United States and to support Sobi's commercialization efforts in the rest of the world. We submitted a new drug

application, or NDA, to the FDA and a marketing authorization application, or MAA, to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the Prescription Drug User Fee Act, or PDUFA, target action date for May 14, 2021. 950

- ***Continue clinical development of systemic pegcetacoplan in other indications, including ALS and C3G/IC-MPGN.*** We are developing pegcetacoplan for patients with C3G and C3G/IC-MPGN, administered by subcutaneous injection. Sobi has primary responsibility for the clinical development pegcetacoplan for patients with CAD and HSCT-TMA.
- ***Continue development and expansion of our pipeline.*** We plan to continue development of treatments for a broad range of complement-dependent autoimmune and inflammatory diseases with pegcetacoplan and additional new product candidates.

Our Programs

Our lead product candidate, pegcetacoplan, is a C3 inhibitor. Pegcetacoplan is a conjugate of a compstatin analogue, formulated both for ophthalmological administration by injections directly into the eye, and systemic administration by subcutaneous injection, which is an injection into the tissue under the skin. We are developing pegcetacoplan and other product candidates, including APL-9, targeting C3 through various routes of administration.

The following table summarizes key information about our ongoing clinical programs:

Program	Clinical Trials	Trial Participants	Estimated Timeline
		Ophthalmological pegcetacoplan	
GA	Phase 3 trials (DERBY/OAKS)	Patients with GA	Top-line data expected 3Q 2021
	Phase 2 trial (FILLY)	Patients with GA	Data reported in Aug 2017
	Phase 1b trial	Patients with low vision GA	Data reported in Apr 2020 and Oct 2020
		Systemic pegcetacoplan	
PNH	Phase 3 trial (PEGASUS)	Eculizumab-treated patients with PNH	Data reported in Jan 2020 and in Dec 2020
	Phase 3 trial (PRINCE)	Treatment-naïve patients with PNH	Top-line data expected 1H 2021
C3G/IC-MPGN	Phase 2 Trial (DISCOVERY)	Patients with glomerular diseases with complement involvement	Data reported Oct 2020
	Phase 2 Trial (NOBLE)	Patients with post-transplant recurrence of C3G or IC-MPGN	First patient treatment expected 1H 2021
	Phase 3 Trial	Patients with native kidney or post-transplant recurrence of C3G or IC-MPGN	Plan to initiate 2H 2021
ALS	Phase 2 Trial (MERIDIAN)	Patients with sporadic ALS	Complete enrollment 2H 2021
CAD	Phase 2 Trial (PLAUDIT)	Patients with CAD and wAIHA	Data reported Jun 2019
	Phase 3 Trial	Patients with CAD	Plan to initiate 2021 (Sobi)
HSCT-TMA	Phase 2 Trial	Patients with HSCT-TMA	Plan to initiate 2021 (Sohi)
		Pipeline	
ARDS	Phase 2 trial	COVID patients	Top-line data reported 2Q 2021

Ophthalmological pegcetacoplan

We are developing pegcetacoplan to be injected intravitreally as a monotherapy for patients with ophthalmological indications, including geographic atrophy, or GA.

Geographic Atrophy

Background

GA is a type of advanced age-related macular degeneration, or AMD. According to the Brightfocus Foundation, over ten million people in the United States have some form of AMD. AMD is a disorder of the central portion of the retina in the eye, known as the macula, which is responsible for central vision and color perception. AMD affects vision in one or both eyes and results in progressive and chronic degeneration of the macula, often resulting in irreversible vision loss. AMD is a disease of aging, typically occurring after

the age of 50. In the early stage of the disease, yellow deposits, or drusen, appear under the retina. Over time, the disease can progress to an intermediate stage where drusen deposits grow larger and other changes reflective of disease progression appear and then to an advanced stage associated with progressive and often severe vision loss which may be characterized as either GA or wet AMD. GA is characterized by a degenerative process resulting in the progressive loss of retinal cells, which over the course of several years results in blindness. Based on published studies, we believe that at least five million people worldwide, including at least one million people in the United States, including have GA.

At the American Academy of Ophthalmology, or AAO, in November 2020, a retrospective study of 69,000 patients diagnosed with GA was presented that analyzed changes in visual acuity and disease progression over two years. The analysis was presented by Verana Health, a data analysis group in retinal diseases under a collaboration with us, and the AAO's IRIS® (Intelligent Researcb in Sight) Registry, the nation's first comprehensive clinical registry for eye disease. Key findings from the real-world clinical data showed:

- At the first study visit, patients presented with relatively preserved vision, especially in eyes with extrafoveal GA lesions (lesions outside the fovea, which is the central portion of the retina). However, patients with extrafoveal and foveal GA lesions progressively lost vision over time at a rate of approximately five letters on a vision chart per year.
- Progression from GA to new onset wet AMD was observed in 4.7% of patients with bilateral GA (GA in both eyes) and 13.3% of patients with wet AMD in the contralateral eye (AMD in the non-treatment eye) during the first 12 months. The rate at 24 months was 8.2% and 21.6% in bilateral GA and wet AMD in the contralateral eye, respectively.
- A large proportion of GA patients did not return for a follow-up visit after two years. Of the GA patients potentially eligible for inclusion in the analysis, only 40% had a follow-up visit after two years and were ultimately included in the study.

The mechanism by which complement activation is upregulated and can damage the retina is poorly understood. However, we believe that the upregulation of complement activation due to immune dysregulation damages retinal cells in two ways. First, retinal cells are damaged by inflammation caused by increased levels of C3a and C5a. Second, the increased deposition of C3b on the cell surface of retinal cells caused by complement activation, combined with the limited ability of cells to remove C3 activated fragments such as C3b, leads to the accumulation of C3 fragments on the retinal cells. The presence of C3a and C5a, as well as C3 fragment deposition on retinal cells, activates macrophages and microglia. Macrophages are large white blood cells that form part of the immune system that engulf and digest cells, debris and foreign substances. Macrophages also play an important role in modulating other parts of the immune system. Microglia are a type of tissue-residing macrophage located in the brain, spinal cord and retina.

Because pegcetacoplan both blocks the production of C3a and C5a and prevents the accumulation of C3 fragments on retinal cells through the inhibition of C3, we believe that pegcetacoplan may control complement activation in the retinal environment to return it to its quiescent state. We do not believe that selective inhibitors of the alternative pathway, which would only partially block the formation of C3b on the retinal cell surface, or C5 inhibitors, which cannot prevent C3b deposition on retinal cells, can cause the retinal environment to return to its quiescent state.

Current Therapies and Their Limitations

There are no therapies approved to treat GA. There are, however, therapies in development for GA including a number of product candidates in late stages of clinical development.

Benefits of Our Approach

We believe pegcetacoplan, with its inhibition of complement activation at the level of C3 in the retinal environment, may provide the following benefits:

- *Prevention or reduction of the rate of retinal cell death progression.* We believe pegcetacoplan may mitigate or prevent retinal cell death in GA. In our Phase 2 trial of pegcetacoplan in patients with GA, treatment with pegcetacoplan resulted in a significant reduction in the rate of GA lesion growth over 12 months.
- *Potential application to all patients with GA independent of complement pathway causing disease progression.* Pegcetacoplan, by targeting C3, has been designed to inhibit all three principal complement activation pathways and may therefore be effective in a broad patient population. We believe, based on the genetic marker and other data from our analysis of our Phase 2 trial, that the activity of pegcetacoplan does not depend upon the activation of any particular complement pathway.

Clinical Development

We initiated the DERBY and OAKS Phase 3 clinical trials of pegcetacoplan in patients with GA following completion of our Phase 2 clinical trial in patients with GA, which we refer to as the FILLY trial. In August 2017, we completed the primary endpoint analysis for the 12-month treatment period for the Phase 2 FILLY trial and in February 2018 we completed the analysis of data from the six-month monitoring period from that trial. Prior to the FILLY trial, we completed a Phase 1 clinical trial of pegcetacoplan in patients with wet AMD in 2016. In July 2018, we received fast track designation from the FDA for pegcetacoplan in GA.

Phase 3 Clinical Trials

Our ongoing Phase 3 clinical program in GA consists of two 600-patient prospective, multicenter, randomized, double-masked, sham-injection controlled trials (DERBY and OAKS) being conducted at 200 sites worldwide to assess the efficacy and safety of multiple intravitreal injections of pegcetacoplan in patients with GA. Both trials are fully enrolled and we expect to announce top-line data from these trials in the third quarter of 2021.

Patients in each Phase 3 trial receive a dose of 15 mg of pegcetacoplan injected intravitreally in a 0.1 cc volume, monthly or every other month for 24 months. In the sham-injection coborts, patients receive a simulated injection. As with our Phase 2 clinical trial, the primary endpoint of each trial is the change in total area of GA lesions in the study eye from baseline to month 12 compared to sham. The measurements of cbange in lesion size will be analyzed at 12 months (primary endpoint, monthly group) and 24 months. We set statistical significance as a p-value of 0.05 or less, meaning that there is a 1 in 20 or less probability that the observed results occurred by chance. Patients wbo develop new onset exudation in the study eye will continue to be treated with pegcetacoplan along with anti-VEGF injections, the current standard of care for wet AMD.

The observation intervals in pivotal studies in AMD are typically 24 months in total duration to meet regulatory requirements for long-term safety and to demonstrate durability of the treatment effect on anatomical and functional endpoints. However, based on our experience in the Phase 2 FILLY trial, we believe that pegcetacoplan can show treatment effect at 12 months and we therefore plan to analyze the data after all patients have completed 12 months of treatment in the trial in addition to a second assessment after 24 months of treatment. This design is in line with the recommendations of the FDA and the EMA.

We are using a liquid formulation of pegcetacoplan in our Phase 3 trials instead of the freeze-dried formulation that we used in the Phase 2 FILLY trial, wbich we believe may reduce the incidence of endophthalmitis.

In October 2018, we announced that we voluntarily implemented a pause in dosing in our Phase 3 clinical trials in patients with GA due to observed cases of non-infectious inflammation in patients treated from a single manufacturing lot of pegcetacoplan intravitreal drug product. Four patients in the Phase 3 GA program were treated with pegcetacoplan from this manufacturing lot and each patient developed non-infectious inflammation. Inflammation in all patients completely resolved. We reviewed these events with the data safety monitoring board for our GA trials, conducted a series of non-human studies and introduced improvements to the manufacturing process. Based on these efforts, we believe that the source of inflammation resided in a contaminant or impurity in the active pharmaceutical ingredient. We resumed the trials in March 2019.

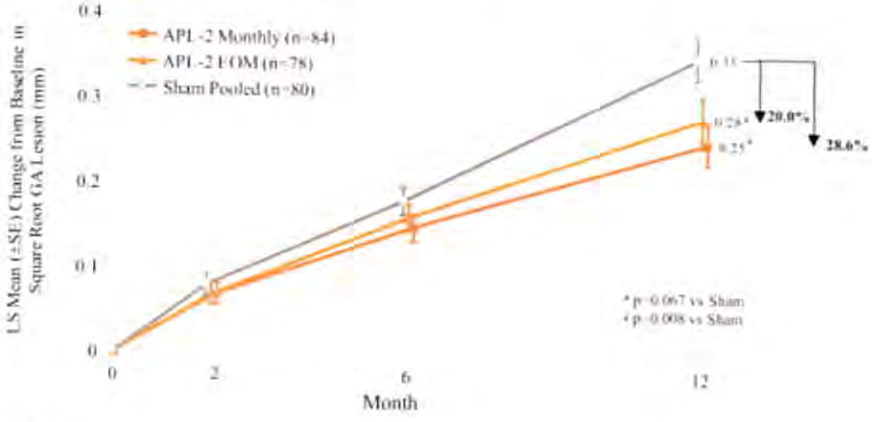
Phase 2 Clinical Trial

In the third quarter of 2015, we initiated a Phase 2 multicenter, randomized, single-masked, sbam-controlled clinical trial of pegcetacoplan in patients with GA, which we refer to as the FILLY trial, at more than 40 clinical sites, primarily located in the United States. We enrolled 246 patients in the trial. Patients were randomized in a 2:2:1:1 manner to receive pegcetacoplan monthly, pegcetacoplan every other month, sham injection monthly or sbam injection every other month. Patients in the pegcetacoplan arms received a dose of 15 mg of pegcetacoplan injected intravitreally in a 0.1 cc volume, monthly or every other month for 12 months followed by six months of monitoring without treatment. In the sham-injection cohorts, patients receive a simulated injection. Study eyes received up to 13 injections in the monthly arm, and up to seven injections in the every other month arm. Eyes were evaluated for GA at the end of months two, six, 12 and 18.

We conducted this trial to assess the safety, tolerability, pharmacokinetics, or PK, and evidence of activity of multiple intravitreal injections of pegcetacoplan in patients with GA in at least one eye. The primary efficacy endpoint was change in the square root of GA lesion size from baseline to month 12 in each treatment arm when compared to sham in the modified intent to treat population, which included 84 patients receiving administration of pegcetacoplan every month, 78 patients receiving administration of pegcetacoplan every other month and 80 patients in the group receiving sham injections. The primary safety endpoint was the number and severity of local and systemic treatment emergent adverse events. The trial was monitored by a safety monitoring committee.

We announced 12-month results of the Phase 2 trial in August 2017. After 12 months, patients treated monthly with pegcetacoplan showed a 29% reduction in the rate of GA lesion growth compared to sham, with a p-value of 0.008, and patients treated every other month showed a 20% reduction compared to sham, with a p-value of 0.067. The rate of GA lesion growth in the

sham was consistent with the rate of lesion growth in patients with GA in third-party historical studies. These data are shown in the figure below. 953



EOM = Every other month

We set statistical significance as a p-value of 0.1 or less, meaning that there is a 1-in-10 or less statistical probability that the observed results occurred by chance rather than as a result of a treatment effect. Because the p-value of these results was less than 0.1, they are statistically significant.

After the 12-month treatment period, patients were monitored for a further six months without treatment. During the monitoring period, the GA lesions in the previously treated groups grew at a rate similar to sham but the treatment effect was maintained for the full 18 months. Patients who received monthly pegcetacoplan, and for whom images were available at 12 and 18 months showed a 12% reduction in the growth rate of lesions over the six-month monitoring period compared to sham, while patients who received every other month administration of pegcetacoplan showed a 9% reduction in the growth rate of lesions over the six-month monitoring period compared to sham. These differences are not considered to be statistically significant. In the modified intent to treat population over the full 18-month period, patients who received monthly pegcetacoplan showed a 20% reduction in the growth rate of lesions over the full 18-month period compared to sham, while patients who received every other month administration of pegcetacoplan showed a 16% reduction in the growth rate of lesions over the full 18-month period compared to sham.

The most frequently reported adverse events in the trial were associated with the injection procedure in the study eye. These adverse events included two cases of confirmed endophthalmitis and one case of presumed endophthalmitis where the culture tested negative for bacterial growth. In the latter case, the patient fully recovered visual acuity. In our Phase 2 trial, we observed an incidence rate of endophthalmitis of 0.21% per injection.

In addition, during the 12-month treatment period and the six-month monitoring period, we observed a higher incidence of new onset exudation in the study eyes treated with pegcetacoplan as compared to sham, predominantly in patients with a history of wet AMD in the fellow eye. Specifically, we observed that, after the 12-month treatment period and the six-month monitoring period, 18 patients (21%) receiving administration of pegcetacoplan every month and seven patients (9%) receiving administration of pegcetacoplan every other month showed new onset exudation in the study eye, as compared to one patient (1%) in the sham group.

Patients who experienced new onset exudation in the study eye were discontinued from treatment with pegcetacoplan and, in all but one case, treated with standard of care anti-VEGF injections under supervision. There was no meaningful negative impact on visual acuity resulting from the new onset exudations.

Phase 1b Clinical Trial in Low Vision Geography Atrophy

We are conducting a Phase 1b clinical trial to evaluate the safety of monthly intravitreal treatments with pegcetacoplan in 12 patients with bilateral GA secondary to AMD and with low vision, which we initiated in September 2018. Patients are dosed monthly with pegcetacoplan in one eye using the fellow eye as an untreated control. In April 2020, we reported results in patients demonstrating a trend in reduced GA lesion growth in treated eyes versus the lesion growth in untreated fellow eyes. In October 2020, we reported data from an 18-month post hoc analysis based on the seven study patients for whom data were available for at least 18 months. In this population, the growth rate of GA lesions in the treated eye was on average 52% (mean square root) slower than the untreated fellow eye (p=0.01). It has been shown in third-party studies that lesions in both eyes tend to grow at the same rate in

patients with bilateral GA. Of the 12 enrolled patients, there were no reported cases of inflammation and one patient (8%) developed new-onset exudation at month 12.

Phase 1b/2 Clinical Trial in Wet AMD

We conducted a Phase 1b/2, multi-center, open label clinical trial to evaluate the safety of intravitreal pegcetacoplan therapy when administered in parallel with anti-VEGF treatments in patients with wet AMD in the study eye in the second quarter of 2018. As with our Phase 3 program in GA, we voluntarily implemented a pause in our Phase 1b/2 trial of pegcetacoplan in patients with wet AMD in October 2018. We discontinued the Phase 1b/2 trial of pegcetacoplan in patients with wet AMD.

Phase 1 Clinical Trial

We conducted a Phase 1 open label, ascending single-dose clinical trial of pegcetacoplan administered by intravitreal injection in patients with wet AMD who were receiving anti-VEGF therapy. We conducted the trial at multiple clinical sites both within and outside the United States to assess safety, tolerability and PK of pegcetacoplan. In this trial, patients received a single dose of pegcetacoplan by intravitreal injection followed by 113 days of monitoring. We enrolled eighteen patients in the trial, in three cohorts, at doses of 5 mg (3 patients), 10 mg (3 patients) and 20 mg (12 patients) of pegcetacoplan. Pegcetacoplan was well tolerated, and no serious adverse events were reported. Based on the results, we determined to evaluate a dose of 15 mg in our Phase 2 trial.

Preclinical Studies

We have conducted preclinical studies in monkeys to assess the safety of pegcetacoplan injected intravitreally. A full toxicological review, including histopathological examinations of both eyes and of multiple additional tissues from each monkey revealed no evidence of pegcetacoplan -related toxicity changes at any of the doses tested.

Systemic Pegcetacoplan

We and Sobi plan to jointly advance the clinical development of systemic pegcetacoplan in five parallel registrational programs across hematology, nephrology, and neurology. These include new registrational programs in CAD and HSCT-TMA. We will lead clinical development for PNH, C3G/IC-MPGN and ALS, and Sobi will lead development activities for a Phase 3 trial in CAD and a Pbase 2 trial in HSCT-TMA, both planned to start in 2021.

Paroxysmal Nocturnal Hemoglobinuria

Background

PNH is a rare, chronic, debilitating blood disorder that is most frequently acquired in early adulthood and usually continues throughout the life of the patient. Some of the prominent symptoms of PNH include severe anemia, a condition that results from having too few red blood cells, severe abdominal pain, severe beadaches, back pain, excessive weakness, fatigue and recurrent infections. If not treated, PNH results in the death of approximately 35% of affected individuals within five years of diagnosis and 50% of affected individuals within ten years of diagnosis, primarily due to the formation of life-threatening blood clots inside the blood vessels, or thrombosis. Based on prevalence data published in an abstract in a peer-reviewed journal, we estimate that there are approximately 4,700 patients with PNH in the United States and approximately15,000 patients with PNH worldwide.

PNH is caused by the presence of mutant stem cells in the bone marrow that lack important proteins on their surface that protect against activation of the complement system. In patients with PNH, an autoimmune response targets and eliminates normal stem cells, enabling mutant cells to become dominant in the bone marrow. These mutant stem cells lead to mutant platelets and red blood cells that, unlike normal cells, are overly susceptible to activation or destruction by the complement system. Mutant platelets, activated by the membrane attack complex, increase the risk of thrombosis, which is the leading cause of mortality in patients with PNH. Mutant red blood cells are susceptible to destruction by intravascular and extravascular hemolysis. Intravascular hemolysis, whicb involves the destruction of blood cells within the blood vessels, is caused by the formation of the membrane attack complex on the surface of red blood cells causing them to rupture. Intravascular hemolysis causes severe anemia and contributes to the risk of thrombosis. Extravascular bemolysis, which involves the destruction of blood cells outside the blood vessels, is caused by C3-related opsonization on red blood cells leading to removal of the cells from the blood stream by the liver and the spleen. Extravascular hemolysis further contributes to severe anemia and transfusion dependency in patients with PNH.

Current Therapies and Their Limitations

Eculizumab, marketed as Soliris, and ravulizumab, marketed as Ultomiris, both by Alexion Pharmaceuticals, Inc., or Alexion are the only therapies that have been approved for the treatment of PNH. Eculizumab, which is administered every two weeks

intravenously, or directly into the veins, is designed to treat PNH by targeting C5 and preventing the formation of the membrane attack complex and intravascular hemolysis. Many patients with PNH on treatment with eculizumab continue to be anemic. Ravulizumab is administered intravenously every week and subcutaneously once per week and is designed to have a longer half-life and greater inhibition of C5 than eculizumab. Ravulizumab was tested in two Phase 3 non-inferiority trials with eculizumab and was found to be non-inferior to eculizumab. 955

Retrospective third-party studies have reported that up to 70% of patients with PNH who are on treatment with eculizumab remained anemic and up to 36% of patients on eculizumab continued to require at least one transfusion per year. In these studies, 100% of patients with PNH on eculizumab showed evidence of C3-related opsonization on their red blood cells. We believe that uncontrolled extravascular hemolysis is responsible in part for these continuing complications.

Benefits of Our Approach

We believe that, because pegcetacoplan inhibits complement activation at the level of C3, pegcetacoplan may provide the following benefits in controlling PNH:

- *Prevention of intravascular hemolysis and its consequences*. Pegcetacoplan may prevent the formation of the membrane attack complex on blood cells and may thereby prevent the activation of mutant platelets and intravascular hemolysis, thus reducing the risk of thrombosis, the leading cause of mortality in PNH, as well as reducing anemia.
- *Prevention of extravascular hemolysis and its consequences*. Pegcetacoplan may prevent C3b opsonization, on blood cells, and may thereby prevent extravascular hemolysis, further reducing anemia and transfusion dependency in patients with PNH.
- *Ease and convenience of use*. We believe that the ability to self-administer pegcetacoplan by subcutaneous injection on a regular basis could improve the quality of life for patients with PNH by eliminating the need to travel to a health care facility for intravenous treatment.

Regulatory Matters

We submitted an NDA to the FDA and an MAA to the EMA for pegcetacoplan for the treatment of PNH in September 2020. The FDA accepted the NDA and set the PDUFA target action date for May 14, 2021. The EMA validated the MAA in October 2020, with the potential for a European Commission decision on the MAA in the second half of 2021.

In April 2014, we received orphan drug designation from the FDA for pegcetacoplan for PNH. In February 2019 we received fast track designation from the FDA for pegcetacoplan for patients with PNH, which superseded the fast track designation we received in December 2016 for pegcetacoplan for the subset of patients with PNH who continue to require transfusions despite receiving therapy with eculizumab.

Clinical Development

If we are able to obtain marketing approval for pegcetacoplan for PNH, we plan to allow PNH patients on treatment with eculizumab to assess the benefit of pegcetacoplan in co-treatment with eculizumab for a limited time, before deciding to switch to pegcetacoplan monotherapy or to revert to eculizumab monotherapy.

If pegcetacoplan is approved for the treatment of patients with PNH, we believe that pegcetacoplan could be a best-in-class therapy for PNH, differentiated by mechanism, and that pegcetacoplan has the potential to significantly increase the quality of life of patients with PNH as compared to the current standard of care.

Phase 3 Clinical Trial - PEGASUS

We initiated the Phase 3 PEGASUS trial in patients in June 2018. The PEGASUS trial was an 80-patient randomized head-to-head trial comparing pegcetacoplan monotherapy to eculizumab monotherapy in patients with PNH currently on treatment with eculizumab who have a hemoglobin level of less than 10.5 g/dL, regarding of eculizumab dose or transfusion history. The primary efficacy endpoint of the trial was the change in hemoglobin level from baseline at week 16.

The treatment period of the trial consisted of three parts: a four-week run-in period, a 16-week randomized treatment period and a 32-week open-label pegcetacoplan only period. During the run-in period, all patients received twice-weekly subcutaneous doses of 1,080 mg of pegcetacoplan in addition to patients' then current dose of eculizumab. The run-in period was designed to provide patients with sufficient plasma concentration of pegcetacoplan to provide for what we expected to be adequate complement inhibition before withdrawing eculizumab. Following completion of the run-in period, patients received either 1,080 mg of pegcetacoplan twice per week or their current dose of eculizumab through the duration of the 16-week randomized treatment period. Following completion

of the randomized treatment period with either pegcetacoplan monotherapy or eculizumab monotherapy, all 80 patients had the option to receive pegcetacoplan monotherapy for 32 weeks in an open-label treatment period.

In January 2020, we announced top-line data from the PEGASUS trial that showed that pegcetacoplan met the primary efficacy endpoint, demonstrating superiority to eculizumab with a statistically significant improvement in adjusted means of 3.8 g/dL of hemoglobin at week 16 ($p < 0.0001$). At week 16, pegcetacoplan-treated patients (n = 41) had an adjusted mean hemoglobin increase of 2.4 g/dL from a baseline of 8.7 g/dL, compared to eculizumab-treated patients (n = 39) who had a change of -1.5 g/dL from a baseline of 8.7 g/dL. Additionally, pegcetacoplan showed promising results in key secondary endpoints. Pegcetacoplan met non-inferiority on transfusion avoidance and absolute reticulocyte count. Pegcetacoplan did not meet pre-specified criteria for non-inferiority on mean LDH levels. Pegcetacoplan showed positive trends on LDH and fatigue as measured by the FACIT-fatigue score. The statistical analysis plan for the PEGASUS trial provided for use of the mixed model—repeated measures (MMRM) method. To avoid the effect of transfusions in hemoglobin levels during the 16-week randomization period of the trial, if a patient received a transfusion during the 16-week randomization period, any measurements after the first transfusion were censored from the data used in the MMRM analysis. The treatment effects using observed data from the trial, which included all post-transfusion measurements, were consistent with and supportive of the reported results from the MMRM analysis.

All patients who completed the 16 week randomization period in both groups (77/80) entered the 32-week open-label pegcetacoplan treatment period. At week 48, patients treated with pegcetacoplan during the 16 week randomization period and through the 32 week open-label period sustained increases in hemoglobin levels, with a mean improvement from baseline of 2.7 g/dL, equal to the 2.7 g/dL mean increase seen at week 16 in the same patients. Additionally, patients treated with eculizumab in the randomized period who switched to pegcetacoplan during the open-label period experienced sustained improvements in hemoglobin and other hematological and clinical measures, similar to patients treated with pegcetacoplan monotherapy during the randomized controlled period. In addition to a sustained improvement in hemoglobin, the pegcetacoplan-treated patients group maintained improvements across key secondary endpoints. Througbout the 48-week study, 73% of patients treated with pegcetacoplan during the randomized period remained transfusion free. For comparison, 25% of patients were transfusion free over the year prior to entering the PEGASUS study while on treatment with eculizumab. Improvements across additional markers of disease, such as reticulocyte count, lactate dehydrogenase, or LDH, levels, and the FACIT-fatigue scores, were observed in both groups at week 48 after 32 weeks of open-label treatment with pegcetacoplan.

In the PEGASUS trial, the safety profile of pegcetacoplan was comparable to eculizumab and consistent with previously reported data. After the 48-week study period, twenty-four of 80 pegcetacoplan monotherapy-treated patients (30%) experienced a serious adverse event (SAE). Five of the SAEs (6%) were assessed to be possibly related to study treatment. No cases of meningitis were reported. One death was reported due to COVID-19 and was unrelated to study treatment. The most common adverse events (AEs) reported throughout the study were injection site reactions (36%), hemolysis (24%), and diarrhea (21%). Twelve out of 80 patients (15%) discontinued due to adverse events, with five discontinuations due to hemolysis. Sixty-four of the 67 patients (96%) who completed the open-label period opted to enter the extension study.

Phase 3 Clinical Trial – PRINCE

We initiated the Phase 3 PRINCE trial in September 2019. The PRINCE trial is a 54-patient randomized, multicenter, open-label trial to evaluate the efficacy of pegcetacoplan in treatment-naïve PNH patients. The primary endpoints are avoidance of a greater than 1 g/dL decrease in hemoglobin level from baseline in the absence of transfusion through week 26 and reduction in LDH level from baseline to week 26, in patients with PNH who are currently not being treated with complement inhibitors. Secondary endpoints include hemoglobin response (defined as an increase in hemoglobin levels greater than or equal to 1 g/dL), change in absolute reticulocyte count, change in hemoglobin levels, number of packed red blood cells transfused, change in FACIT score, hemoglobin normalization and LDH normalization. This trial is fully enrolled and we expect to present top-line data in the second quarter of 2021.

Phase 1b Clinical Trials – PHAROAH and PADDOCK

Prior to commencing our two Phase 3 trials, we conducted two clinical trials of pegcetacoplan as part of our PNH program: a Phase 1b clinical trial (PHAROAH) in patients with PNH being treated with eculizumab, which has concluded, and a Phase 1b clinical trial (PADDOCK) in treatment-naïve patients. These trials were designed to assess safety and tolerahility and whether pegcetacoplan has the potential to control PNH. In these trials, we measured hemoglobin levels, which are significantly lower in patients with PNH, whether or not treated with eculizumah, and blood reticulocyte count, which is an indicator of overall hemolysis (both intravascular and extravascular) in patients on eculizumab. We also measured intravascular hemolysis based on LDH levels, which can be ten times higher than normal in patients with PNH, bilirubin, which is a breakdown product of hemoglobin and may be higher in patients who experience hemolysis, and the clonal distributions of normal red blood cells and mutant red blood cells unprotected from the membrane attack complex.

PHAROAH was a Phase 1b open-label, single and multiple ascending dose clinical trial of pegcetacoplan in patients with PNH who are receiving eculizumab, conducted at multiple clinical sites in the United States. In the PHAROAH trial, doses of pegcetacoplan

Attachment F

Regarding the Fingerprints and Surety Bond

APL Sales I LLC is ultimately owned by Apellis Pharmaceuticals, Inc., a public company trading on the NASDAQ. As confirmed by your office, fingerprints and a surety bond are not required for an applicant that is owned by a publicly traded company. Enclosed please find documentation showing the ownership.

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Applied Therapeutics, Inc.

Physical Address: 600 Palisades Avenue, Ste 22

City: Englewood Cliffs State: NJ Zip Code: 07632

Telephone Number: (201) 618-8888 Fax Number: _____

Toll Free Number: _____

E-mail: statelicensing@appliedtherapeutics.com Website: https://appliedtherapeutics.com/

Facility Manager: Robert Holmes

Professional qualifications and experience of facility manager: Robert Holmes is at least 21 years of age and has been employed full-time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs. Robert Holmes is currently employed by Applied Therapeutics, Inc. full time in a managerial level and is actively involved in and aware of the actual daily operation of the wholesale distributor. Robert Holmes is physically present at the facility during regular business hours, except when an absence has been authorized.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Adam Hansard
Print Name of Authorized Person

4/14/2021
Date

Board Use Only Date Processed: 5/26/2021 ✓ Amount: 500
Check #3884130

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: N/A

Corporation Name: Applied Therapeutics, Inc.

Mailing Address: 600 Palisades Avenue, Ste 22

City: Englewood Cliffs State: New Jersey Zip: 07632

Telephone: (201) 618-8888 Fax:

Contact Person: Robert Holmes

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 5/13/2019

Registration number issued: CIK: 0001697532. See Attached

Stock Exchange: APLT

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0744282

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

600 PALISADES AVE, STE 22 ENGLEWOOD CLIFFS, NJ 07632-

Reg. No.
5005875

APPLIED THERAPEUTICS, INC.
600 PALISADES AVE, STE 22
ENGLEWOOD CLIFFS, NJ 07632-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 5/17/2021

Registration Number: 5005875 **Registered as:**

Name: APPLIED THERAPEUTICS, INC.

DBA:

Address: 600 PALISADES AVE, STE 22, ENGLEWOOD CLIFFS, NJ 07632

Original Issue Date: 03/26/2021 **Expiration Date:** 01/31/2022

Current Issue Date: 03/26/2021

Disciplines: No

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "APPLIED THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "APPLIED THERAPEUTICS, INC." WAS INCORPORATED ON THE TWENTIETH DAY OF JANUARY, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5942155 8300

SR# 20211410489

Authentication: 203035018

Date: 04-22-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

APPLIED THERAPEUTICS

Corporate Information

Applied Therapeutics, Inc.
600 Palisades Avenue, Ste 22
Englewood Cliffs, NJ 07632
Phone: (201) 618-8888
Website: www.appliedtherapeutics.com
E-mail: statelicensing@appliedtherapeutics.com

FEIN: 81-3405262
State of Formation: Delaware
Date Incorporated: 01/20/2016
File Number: 5942155

Ownership Information

Applied Therapeutics, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol APLT.

Officers

Shoshana Shendelman, Chief Executive Officer
Business Address: 545 Fifth Ave, Ste 1400, New York, NY 10017
Business Phone: (212) 220-9319

Charles Silberstein, Chief Financial Officer
Business Address: 545 Fifth Ave, Ste 1400, New York, NY 10017
Business Phone: (201) 618-8888

Adam Hansard, Chief Commercial Officer
Business Address: 545 Fifth Avenue, Suite 1400, New York, NY 10017
Business Phone: (646) 974-9134

Riccardo Perfetti, Chief Medical Officer
Business Address: 545 Fifth Avenue, Suite 1400, New York, NY 10017
Business Phone: (347) 702-3018

ROBERT HOLMES

[redacted] • Pottersville, NJ 07979 | p [redacted] | e [redacted]

- **Vice President with 20 years of pharmaceutical experience within the areas of sales, market access, trade and distribution, reimbursement, and patient support. Proven success leading patient access and support, marketing, operations, trade, and product launch efforts to drive revenue and market share**
- **Engages stakeholders and key decision-makers across an organization to generate consensus and initiate change**
- **Expertise in managing large-scale budgets, leading tactical and strategic planning, and establishing measurements for program outcomes and effectiveness. Spearheads operational process improvements to maximize product and program success**
- **Recognized as an empowering leader with experience hiring, developing, and motivating high-performing teams**
- **Translates complex data into actionable insights to inform strategic investments and decision making**
- **Champion of innovative solutions to solve complex problems and optimize impact**

AREAS OF EXPERTISE

Patient Access & Reimbursement Programs | Product Acquisition – Medical Benefit/Buy and Bill | Operations Management | Revenue Forecasting / P&L Management | Orphan Drug / Rare Disease | Trade and Distribution
Budget Development & Allocation | Product Development & Marketing | New Product Launch | Customer Retention Productivity & Process Improvements | Data Analysis | Market Research & Intelligence | Advisory Boards
Technology Assessment & Implementation | Channel Strategy Development | Program and Field Leadership & Training

PROFESSIONAL EXPERIENCE

APPLIED THERAPEUTICS | New York, NY **2020 - Present**

Vice President, Patient and Provider Services **2020 - Present**
Responsible for the strategic and operational leadership of the Applied Therapeutics Patient and Provider Services Program. Organizational responsibilities include: Applied Therapeutics Integrated Specialty Pharmacy and Patient Support Center(HUB), warehousing and distribution strategy and operations – third party logistics (3PL), and development of home office/field patient and provider services personnel. Ensure cross-functional executive alignment on the development and design of solutions that improve patient access and experience.

- Lead integrated Specialty Pharmacy/Patient Support Center(HUB)/Third Party Logistics (3PL) partner identification and selection process
- Established initial three-year patient and provider services operating budget to support the launch of Applied Therapeutics initial product launch in rare disease
- Initiated and lead state licensure process for Applied Therapeutics ensuring the ability to ship and sell product in all fifty states
- Lead product serialization project ensuring that Applied Therapeutic's products can be electronically identified, tracked and traced ensuring compliance with Drug and Supply Chain Security Act (DSCSA)
- Lead workstream to relocate Applied Therapeutics resident state to New Jersey to ensure ability to launch products on time
- Designed and developed Applied Therapeutic Patient Support Strategy and Tactical Plan aligned with the intended patient journey

CELGENE (Bristol Meyers Squibb Company) | Summit, NJ **2018 - 2020**

Executive Director, Patient Access Services and Support – Hematology/Oncology **2018 – 2020**
Responsible for leadership, operation and strategic direction of the CELGENE PATIENT SUPPORT program. Organizational responsibility includes 52 Celgene employees and 25 contracted field reimbursement managers supported by a $70M budget. Ensure cross-functional executive alignment on the development and design of solutions improving the patient experience across the hematology/oncology franchise. Responsible for the strategic and tactical alignment of cross-company executive alliance partners.

- Led redesign and development of the CELGENE PATIENT SUPPORT program improving the patient experience through the implementation of data to measure and manage performance and drive decision making
- Implemented and executed new approach to patient support strategic and tactical launch planning leading to the successful launch of two oncology products: INREBIC (oral) for myelofibrosis and REBLOZYL (HCP administered injection) for beta thalassemia.

- Worked with cross-functionally with the support of legal and compliance partners appropriately revised the field reimbursement manager Rules and Engagement allowing team to more effectively support patients, work more closely with their field matrix partners, and robustly support new launches.
- Successfully integrated new dashboards, key support indicators, and evaluation parameters for the CELGENE PATIENT SUPPORT internal patient support contact center improving overall team performance
- Improved patient outcomes by evolving vendor relationships into strategic partnerships focused on improving the patient experience, removing costs, and driving a mutually beneficial relationship

Key Highlights: received 2019 Celgene Values Award for transformation of CELGENE PATIENT SUPPORT, appointed by SVP of Sales and Marketing to lead integration with BMS, selected and retained by BMS to lead the design and delivery of next generation patient services, design and build of patient services to support MS launch product ZEPOSIA

OTSUKA AMERICA PHARMACEUTICALS, INC. | Princeton, NJ **2013 – 2018**

Senior Director, Patient Access and Support **2017 - 2018**

Promoted to Head of ASSURE Patient Support Program responsible for a team of 59 field and 8 in-house personnel effectively managing a budget of ~$40 M. Responsible for cross-functional executive alignment across multiple franchises and alliance management across multiple companies. Direct all aspects of strategic planning, tactical execution, investment allocation, and program operations and effectiveness.

- Leading ASSURE Patient Support Evolution: vendor transition and redesign of HUB service model, integration of technology at multiple program points to enable efficiency and improve performance, leveraging behavioral psychology and AI into call center nursing to improve patient outcomes, leveraging data and analytics to inform decisions, gainer deeper business insights and measure/manage performance.
- Removed ~$5.5 million in excessive HUB vendor expenses, while improving service levels through technological innovations
- Implemented ASSURE Patient Support Program Benchmarking Analysis in partnership with Executive Leadership, Legal and Compliance and McKinsey to benchmark manufacturer patient support programs capabilities
- Successfully designed and led execution of patient support launch plan for JYNARQUE for Autosomal Dominant Polycystic Kidney Disease – high cost orphan drug, rare disease, and comprehensive REMS
- Appointed to serve as Vice President of Operations for Otsuka Patient Assistance Foundation an independent 501(c)(3) charitable organization

Key Highlights: Promoted by CEO and SVP of Commercial Operations to Senior Director and Head of ASSURE after serving as interim lead for five months. Removed an excess of ~$5.5M in operational expenses related to vendor spend. Launched ORION a real-time business outcome tool where field personnel can measure and manage their impact on the patients they support. Led ASSURE Program through a time of significant leadership and cultural change and returned business unit to growth.

Director, Patient Access and Support Operations **2015 – 2018**

Promoted into a newly created position guiding strategy, operations, and marketing for the ASSURE Patient Support Program, increasing treatment access for patients. A leader of leaders directing a strategic team and leveraging a 59 member national patient access field team with responsibility for internal/external marketing strategy, operations, legal, performance management, budget development, revenue forecasting, and stakeholder communications.

- Appointed Interim Head of ASSURE after resignation Vice President. Led through a time of substantial change and transition including a field force sizing optimization
- Led project to build field customer facing CRM tool(Ingenius) integrating case management features while simultaneously delivering ORION for field management and personnel to measure and assess their impact and performance
- Successfully redesigned and relaunched the ASSURE Local Care Center program increasing injections from 227 to over 13,000 across 2100+ sites in 24 months.
- Collaborated with government affairs to navigate legislation changes enabling pharmacy administration in eight states; secured partnerships with national, regional, and local pharmacies as approved injection sites.
- Implemented a multi-channel marketing strategy targeting tele-psychiatrists, case managers, private psychiatrists, billing managers, and intake coordinators at private offices, hospitals, pharmacies, clinics, and mobile nursing programs.
- Facilitated cross-functional collaboration to develop tools to measure program impact and field force effectiveness
- Developed an innovative and automated tool to measure and manage patient adherence, ARIA

Key Highlights: Generated $15M in gross revenue from a $1.8M initial program investment, with over ~21,000 injections forecast for 2018. Received the US Leadership Team Award (2016) recognizing successful development and launch of the ASSURE Local Care Center Program. 2017 MMM&M Women to Watch – Hanna Coon ASSURE Marketing. Won Gold Award in the Digital Media Mobile App Category at the 2017 MarCom Awards for the ASSURE LCC Finder App.

Regional Manager, Patient Access and Support **2014 – 2015**

Assembled and led a team of 14 field reimbursement managers within the newly established ASSURE division focused on expanding and improving product and patient access across the East Coast. Developed and refined the ASSURE program to strengthen patient access support during new product launches and for the Abilify MAINTENA brand.

- Partnered with other divisions to structure market-specific strategies, and communicated with sales leadership to access challenges; managed a $2.5M expense and travel budget.
- Trained managers to educate over 2000 customers in 10 states on product and procedure billing, front/back-office processes, remediation solutions, and utilization of wholesalers and specialty pharmacies for procuring medications.
- Educated and interfaced with senior executives, billing managers, administrators, and prescribers at injection sites, hospitals, and health systems.

Key Highlights: Ranked number one based on management objectives after training 14 associates with minimal reimbursement and access experience. Grew percentage of accounts procuring Abilify MAINTENA through medical benefit from 60% to 93% in 12 months. Increased ASSURE program enrollments 400% and improved overall product access.

Field Reimbursement Manager **2013 – 2014**

Led a four-person team as a player/coach. Optimizing reimbursement efforts for therapies impacted by formulary approval status and other critical payer issues. Supported the launch of Ability MAINTENA to improve patient access across the Northeast. Directed tactical execution for the most complex reimbursement market in the US, serving as the access lead for the team tasked with opening Abilify MAINTENA in New York State.

- Focused on creating operational synergies between marketing, commercial, sales, reimbursement, and trade groups.
- Partnered with sales and marketing executives on a new customer service model based on prior success at Janssen.
- Exceeded all sales goals following launch, and proposed regional access strategy to overcome Medicaid exclusion.

Key Highlights: Received highest performance rating within the National Reimbursement Team (2013); earned the SPOT Award for partnership excellence with marketing. Improved medical benefit access to Ability MAINTENA by 60%.

JANSSEN PHARMACEUTICA (Johnson & Johnson Company) | Titusville, NJ **2003 – 2013**

CNS Learning and Development Manager - Reimbursement and Patient Access **2012 – 2013**

Progressed through multiple roles focused on increasing patient access and reimbursement for brands within the Janssen portfolio. Promoted to lead an three-person team supporting the newly established Patient Support Group, and build out a new hire training and development model for continuing education. Managed a $600K program budget.

- Designed new hire and continuing education programs examining sales, patient support, reimbursement, and access topics, later adopted by three other learning and development departments within J&J BioPharma.

Key Highlights: Leveraged technology to create a virtual training environment enabling greater cost savings, engagement, and effectiveness; reduced duration from six to three months by redesigning and customizing the training curriculum to meet individual learning needs and incorporate state-level reimbursement and access policies.

CNS Learning and Development Trainer – Long Acting Therapies **2010 – 2012**

Appointed as an in-house sales trainer to educate field sales teams on best practices for supporting physicians and administrators around complex reimbursement and access issues. Reworked entire training curriculum and agenda to minimize onboarding time for new sales associates, and presented training sessions at national sales meetings.

- Partnered cross-functionally with internal groups at all phases of program design.
- Built out a continuing education training curriculum to support ongoing sales team development.

CNS Senior Area Business Specialist – Reimbursement and Access to Long Acting Therapies **2006 – 2010**

Promoted into a field reimbursement role focused on expanding the footprint, value proposition, and patient access for injectable therapies (INVEGA SUSTENNA and Risperal Consta) throughout Northern New Jersey. Established relationships with key decision makers and healthcare executives within hospitals, health systems, advocacy organizations, and mental health clinic to open and expand access to long injectable therapies.

- Led the opening and expansion of injection clinics and secured formulary approval for therapies in the CNS portfolio.

Key Highlights: Recognized as a top performer at the national, regional, and district levels (2008).

CNS Sales Representative – New York / New Jersey **2003 – 2006**

- Droves sales of anti-psychotic and injectable medications (Risperal and Risperal Consta) to hospitals, clinics, and private practices, managing a portfolio of accounts across the greater New York City area.

Key Highlights: Earned the Field Sales Director Award and President's Trophy as the top 3% of 399 representative.

Previous experience as a Senior Sales Representative *for* ABBOTT LABORATORIES *(2001 – 2003).*

EDUCATION

MA, Chinese History, Minor in International Business | SETON HALL UNIVERSITY
BA, History, Minor in Political Science | GETTYSBURG COLLEGE

APPLIED THERAPEUTICS

Description of Operations

Applied Therapeutics, Inc. is a Virtual Manufacturer. Applied's product is manufactured by a Contract Manufacturer and will be distributed to Specialty Pharmacies by their Third-Party Logistics Provider, Cardinal SPS, who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Patheon Inc
Address: 111 Consumers Drive
Whitby, Ontario, Canada L1N 5Z5
FDA Establishment Number: 3003516812
Contact: Patrick Klassnitz

Patheon Inc manufactures Applied's product and packages finished product. At no time does Patheon own the product, contract with Applied's customers, invoice, nor sell Applieds product. Applied's product is not a Controlled Substances.

Labeler Code:
81134

Third Party Logistic information:
For distribution into the commercial supply channels, a 3PL will act as Applied's Third Party Logistics (3PL) provider to manage the storage and distribution of Applied's product to Specialty Pharmacies throughout the United States

Cardinal SPS
501 Mason Rd.
LaVergne, TN 37086
Joe Bowman
joe.bowman@cardinalhealth.com

Applied's hours of operation are 9:00 am – 5:00pm Monday through Friday.

From: "edrls@fda.hhs.gov" <edrls@fda.hhs.gov>
Reply-To: "edrls@fda.hhs.gov" <edrls@fda.hhs.gov>
Date: Wednesday, November 18, 2020 at 10:41 AM
To: "bmarczi@appliedtherapeutics.com" <bmarczi@appliedtherapeutics.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 18-NOV-2020
Labeler DUNS: 080874091
Labeler Name: Applied Therapeutics, Inc.
Labeler Code Assigned: 81134

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-38898

Applied Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-3405262**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

545 Fifth Avenue, Suite 1400
New York, New York 10017
(212) 220-9226
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001	APLT	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 10, 2020, the registrant had 22,435,414 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

		Page
	Special Note Regarding Forward-Looking Statements	2
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements (Unaudited)	4
	Condensed Balance Sheets	4
	Condensed Statements of Operations	5
	Condensed Statements of Comprehensive Loss	6
	Condensed Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity	7
	Condensed Statements of Cash Flows	9
	Notes to Unaudited Condensed Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	39
Item 4.	Controls and Procedures	40
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	40
Item 1A.	Risk Factors	40
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	81
Item 3.	Defaults Upon Senior Securities	81
Item 4.	Mine Safety Disclosures	81
Item 5.	Other Information	81
Item 6.	Exhibits	81
	Signatures	

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "forecast," "goal," "intend," "may," "objective," "plan," "predict," "positioned," "potential," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, including risks described in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q:

- the potential impact of the Covid-19 pandemic on the timing and progress of our ongoing clinical trials, our business, results of operations, liquidity, and operations and our ability to mitigate those potential impacts;
- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- our ability to take advantage of expedited regulatory pathways for any of our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations and liabilities thereunder;
- developments relating to our competitors and our industry; and
- other factors that may impact our financial results.

The foregoing list of risks is not exhaustive. Other sections of this Quarterly Report on Form 10-Q may include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Unless the context otherwise requires, the terms "Applied," "Applied Therapeutics," "the company," "we," "us," "our" and similar references in this Quarterly Report on Form 10-Q refer to Applied Therapeutics, Inc.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Applied Therapeutics, Inc.
Condensed Balance Sheets
(in thousands, except share and per share data)

	As of June 30, 2020 (Unaudited)	As of December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 100,854	$ 18,850
Investments	37,644	20,004
Prepaid expenses and other current assets	10,026	7,301
Total current assets	148,524	46,155
Operating lease right-of-use asset	1,849	2,035
Security deposits and leasehold improvements	199	199
TOTAL ASSETS	$ 150,572	$ 48,389
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Current portion of operating lease liabilities	372	356
Accounts payable	5,649	8,793
Accrued expenses and other current liabilities	12,855	4,950
Total current liabilities	18,876	14,099
NONCURRENT LIABILITIES:		
Noncurrent portion of operating lease liabilities	1,492	1,683
Total noncurrent liabilities	1,492	1,683
Total liabilities	20,368	15,782
STOCKHOLDERS' EQUITY:		
Common stock, $0.0001 par value; 100,000,000 and 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 22,331,142 shares and 18,531,560 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	237,429	99,378
Accumulated other comprehensive loss	(29)	(2)
Accumulated deficit	(107,198)	(66,770)
Total stockholders' equity	130,204	32,607
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 150,572	$ 48,389

The Notes to Condensed Financial Statements are an integral part of these statements.

Table of Contents

Applied Therapeutics, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
OPERATING EXPENSES:				
Research and development	$ 20,758	$ 4,254	$ 28,028	$ 11,128
General and administrative	7,522	4,183	12,725	6,037
Total operating expenses	28,280	8,437	40,753	17,165
LOSS FROM OPERATIONS	(28,280)	(8,437)	(40,753)	(17,165)
OTHER INCOME (EXPENSE), NET:				
Interest income (expense), net	183	—	304	(1)
Other income (expense)	38	—	21	—
Total other income (expense), net	221	—	325	(1)
Net loss	$ (28,059)	$ (8,437)	$ (40,428)	$ (17,166)
Net loss attributable to common stockholders—basic and diluted	$ (28,059)	$ (8,437)	$ (40,428)	$ (17,166)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.27)	$ (0.60)	$ (1.88)	$ (1.76)
Weighted-average common stock outstanding—basic and diluted	22,062,030	13,945,939	21,451,344	9,776,582

The Notes to Condensed Financial Statements are an integral part of these statements.

Table of Contents

Applied Therapeutics Inc.
Condensed Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net Loss	$ (28,059)	$ (8,437)	$ (40,428)	$ (17,166)
Other comprehensive loss				—
Unrealized loss on marketable securities	(118)	—	(27)	—
Other comprehensive loss, net of tax	(118)	—	(27)	—
Comprehensive income (loss), net of tax	$ (28,177)	$ (8,437)	$ (40,455)	$ (17,166)

The Notes to Condensed Financial Statements are an integral part of these statements.

Table of Contents

Applied Therapeutics, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity
(in thousands, except share and per share data)
(Unaudited)

	Convertible Preferred Stock									
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock $0.0001 Par Value		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
BALANCE, January 1, 2019	3,093,898	$ 6,254	4,001,848	$ 29,156	5,513,531	$ —	$ 1,665	$ (21,257)	$ —	$ (19,592)
Issuance of Series B convertible preferred stock for cash, net of issuance costs of $266	—	—	442,925	3,051					—	—
Issuance of common stock warrants in connection with the issuance of Series B convertible preferred stock	—	—	—	—			80		—	80
Stock-based compensation expense	—	—	—	—			325		—	325
Net loss	—	—	—	—				(8,730)	—	(8,730)
BALANCE, March 31, 2019	3,093,898	$ 6,254	4,444,773	$ 32,207	5,513,531	$ —	$ 2,070	$ (29,987)	$ —	$ (27,917)
Conversion of Series A convertible preferred stock into common stock upon closing of initial public offering	(3,093,898)	(6,254)	—	—	3,093,898	—	6,254	—	—	6,254
Conversion of Series B convertible preferred stock into common stock upon closing of initial public offering	—	—	(4,444,773)	(32,207)	4,444,773	1	32,207	—	—	32,208
Issuance of common stock upon initial public offering, net of issuance costs of $5,383	—	—	—	—	4,000,000	—	34,617	—	—	34,617
Stock-based compensation expense	—	—	—	—	—	—	3,279	—	—	3,279
Net loss	—	—	—	—	—	—	—	(8,437)	—	(8,437)
BALANCE, June 30, 2019	—	$ —	—	$ —	17,052,202	$ 1	$ 78,427	$ (38,424)	$ —	$ 40,004

Table of Contents

	Convertible Preferred Stock									
	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
BALANCE, January 1, 2020	—	$ —	—	$ —	18,531,560	$ 1	$ 99,378	$ (66,770)	$ (2)	$ 32,607
Issuance of common stock upon secondary public offering, net of issuance costs of $714	—	—	—	—	3,152,712	1	134,127	—	—	134,128
Exercise of options for common stock issued under equity incentive plan	—	—	—	—	35,027	0	81	—	—	81
Private placement issuance costs	—	—	—	—	—	—	(41)	—	—	(41)
Exercise of warrants for common stock	—	—	—	—	249,978	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,331	—	—	1,331
Net loss	—	—	—	—	—	—	—	(12,369)	—	(12,369)
Other comprehensive income	—	—	—	—	—	—	—	—	91	91
BALANCE, March 31, 2020	—	—	—	—	21,969,277	2	234,876	(79,139)	89	155,828
Exercise of options for common stock issued under equity incentive plan	—	—	—	—	324,614	—	1,342	—	—	1,342
Private placement issuance costs	—	—	—	—	—	—	(6)	—	—	(6)
Secondary public offering issuance costs	—	—	—	—	—	—	(25)	—	—	(25)
Registration of Form S-3 offering costs	—	—	—	—	—	—	(495)	—	—	(495)
Exercise of warrants for common stock	—	—	—	—	37,251	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,737	—	—	1,737
Net loss	—	—	—	—	—	—	—	(28,059)	—	(28,059)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	(118)	(118)
BALANCE, June 30, 2020	—	—	—	—	22,331,142	2	237,429	(107,198)	(29)	130,204

The Notes to Condensed Financial Statements are an integral part of these statements.

Table of Contents

Applied Therapeutics, Inc.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (40,428)	$ (17,166)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,068	3,604
Amortization of operating lease right-of-use assets	186	—
Change in operating lease liability	(173)	—
Changes in operating assets and liabilities:		
Prepaid expenses	762	(4,330)
Accounts payable	(3,150)	462
Accrued expenses and other current liabilities	4,441	1,369
Amortization of insurance premium	528	—
Net cash used in operating activities	(34,766)	(16,061)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of available-for-sale securities	(17,667)	—
Net cash used in investing activities	(17,667)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of Series B convertible preferred stock, net of cash issuance costs of $186	—	3,131
Proceeds from secondary public offering, net of cash issuance costs of $702	134,127	—
Proceeds from the IPO, net of underwriter commissions	—	37,200
Payment of deferred offering costs	—	(1,942)
Payment of private placement offering costs	(152)	—
Payment of registration statement on Form S-3 offering costs	(168)	—
Financed insurance premium down payment	(793)	—
Exercise of stock options for common stock under equity incentive plan	1,423	—
Net cash provided by financing activities	134,437	38,389
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	82,004	22,328
Cash and cash equivalents at beginning of period	18,850	18,748
Cash and cash equivalents at end of period	$ 100,854	$ 41,076
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Issuance of warrants in connection with Series B convertible preferred stock	$ —	$ 80
IPO costs in accrued expenses	$ —	$ 11
IPO costs in accounts payable	$ —	$ 510
Private placement costs in accrued expenses	$ 43	$ —
Private placement costs in accounts payable	$ 11	$ —
Secondary offering costs still in accrued expenses	$ 25	$ —
Shelf offering costs still in accrued expense	$ 224	$ —
Shelf offering costs still in accounts payable	103	
Insurance premium obtained in exchange for a short-term loan	$ (4,015)	$ —
Unrealized gain (loss) on marketable securities	$ (27)	$ —
Conversion of preferred stock to equity following the IPO	$ —	$ 38,461

The Notes to Condensed Financial Statements are an integral part of these statements.

Applied Therapeutics, Inc.

Notes to Condensed Financial Statements (Unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Operations and Business

Applied Therapeutics, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing a pipeline of novel product candidates against validated molecular targets in indications of high unmet medical need. In particular, the Company is currently targeting treatments for rare metabolic diseases such as galactosemia, and diabetic complications including diabetic cardiomyopathy. The Company was incorporated in Delaware on January 20, 2016 and is headquartered in New York, New York.

On May 16, 2019, the Company completed an initial public offering (the "IPO") in which the Company issued and sold 4,000,000 shares of its common stock at a public offering price of $10.00 per share, for aggregate gross proceeds of $40.0 million. The Company received net of proceeds $34.6 million, after deducting underwriting discounts and commissions and offering costs. Prior to the completion of the IPO, the Company primarily funded its operations with proceeds from the sale of convertible preferred stock (see Note 8).

In connection with the IPO, the Company effected a 55.2486-for-1 stock split of its issued and outstanding shares of common stock and convertible preferred stock. The stock split became effective on April 26, 2019. Stockholders entitled to fractional shares as a result of the forward stock split received cash payment in lieu of receiving fractional shares. All share and per share amounts for all periods presented in the accompanying condensed financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect this stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately increased and the respective per share value and exercise prices, if applicable, were proportionately decreased in accordance with the terms of the agreements governing such securities.

Upon the closing of the IPO on May 16, 2019, all of the then-outstanding shares of convertible preferred stock automatically converted into 7,538,671 shares of common stock on a one-for-one basis. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

On November 12, 2019, the Company completed a private placement (the "Private Placement"), pursuant to which it issued and sold 1,380,344 shares of the Company's commou stock at a price of $14.50 per share, for net proceeds of $18.4 million after deducting placement agent discounts and commissions and offering costs.

On January 28, 2020, the Company completed its secondary public offering (the "Secondary Public Offering"), pursuant to which it issued and sold 2,741,489 shares of common stock at a public offering price of $45.50 per share, with an additional 411,223 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. The aggregate net proceeds received by the Company from the offering, after deducting underwriting discounts and commissions and offering costs, were $134.1 million.

On June 4, 2020, the Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement") under which the Company may, from time to time, sell securities in one or more offerings having an aggregate offering price of up to $300.0 million. The Shelf Registration Statement was declared effective as of June 15, 2020. As of the filing date of this Quarterly Report on Form 10-Q, no securities have been sold under this shelf registration.

On June 12, 2020, the Company entered into an equity distribution agreement (the "Equity Distribution Agreement") with Goldman Sachs & Co. LLC ("Goldman"), as a sales agent to sell shares of the Company's common stock, from time to time, having an aggregate offering price of up to $100 million. Goldman may act as an agent on the Company's behalf or purchase shares of the Company's common stock as a principal. As of June 30, 2020, the Company had no sold any shares of common stock pursuant to the Equity Distribution Agreement.

TwoLabs PHARMA SERVICES

APPLIED THERAPEUTICS

May 20, 2021



Via Fed Ex

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

To Whom It May Concern:

On behalf of Applied Therapeutics, Inc. ("Applied") attached is Applied's Initial application.

Applied is in Englewood Cliffs, NJ and is developing a pipeline of novel products that target molecules and pathways with proven roles in disease biology. Aldose Reductase is an enzyme involved in the pathophysiology of numerous diseases with high unmet medical need. Applied has developed a new generation of ARIs that are in clinical development for conditions such as Galactosemia and Diabetic Cardiomyopathy. Utilizing advanced crystallography, the company has developed a unique understanding of structural changes within the enzyme active site, which has enabled functional design of new compounds to improve binding affinity and specificity. These new compounds have higher Aldose Reductase inhibitory activity and less off-target activity. The leading drug product set for launch October 2021 is AT-007. AT-007 is a potent and selective compound, which crosses the blood brain barrier into the Central Nervous System (CNS penetrant). AT-007 has received both Orphan Drug and Pediatric Rare Disease designations from the FDA for the treatment of Galactosemia, a rare metabolic disease, and Phosphomannomutase 2 Deficiency – a Congenital Disorder of Glycosylation (PMM2-CDG).

Applied is a "Virtual Manufacturer" whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Applied's office. Applied's product is not a controlled substance. At the time of this filing, Applied holds a license in its home state of New Jersey.

I hope this narrative is helpful as you review Applied's application. If you have a question regarding this application, please contact me at 216-406-0178 or via email at cheryl.midian@twolabs.com. Please also address all written communication to me. My address is 4967 Cadogan Place, New Albany, OH 43054.

Thank you in advance for your consideration.

Cheryl Midian
Licensing Analyst
PharmaLicense

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Celgene Corporation

Physical Address: 556 Morris Ave., Building S12

City: Summit State: NJ Zip Code: 07901

Telephone Number: (908) 897-4603 Fax Number: (866) 545-7749

Toll Free Number: N/A

E-mail: jordan.spadafora@twolabs.com Website: https://www.celgene.ca/en/

Facility Manager: Joseph Zielinski, Jr.

Professional qualifications and experience of facility manager:
See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☒ No ☐

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Katherine Kelly
Print Name of Authorized Person

2/12/2021
Date

Board Use Only	Date Processed:_____	Amount: $500 Check # 3543419

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Bristol-Myers Squibb Company

Corporation Name: _____

Mailing Address: 430 E 29th Street, 14th Floor

City: New York State: NY Zip: 10016

Telephone: (908) 897-4603 Fax: N/A

Contact Person: Joseph A. Zielinski Jr.

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 5/07/2010

Registration number issued: 0326501

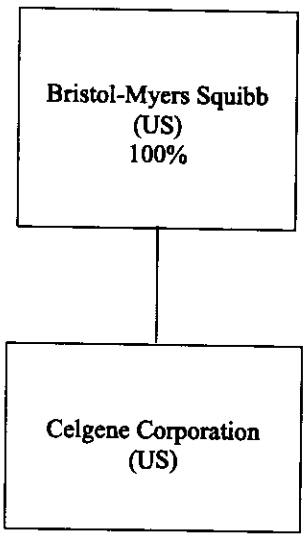
Stock Exchange: BMY

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.


Bristol-Myers Squibb
(US)
100%
Celgene Corporation
(US)

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0741696

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification "

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

86 MORRIS AVE SUMMIT, NJ 07901-
7339 INDUSTRIAL BLVD ALLENTOWN,PA 18106-
556 MORRIS AVE. BLDG S12 SUMMIT, NJ 07901-

Reg. No.
5003533

CELGENE CORPORATION
C/O STATE LICENSE SERVICING
1751 STATE RTE 17A, STE 3
FLORIDA, NY 10921-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CELGENE CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2088605 8300

SR# 20210312371

Authentication: 202428309

Date: 02-02-21

You may verify this certificate online at corp.delaware.gov/authver.shtml



Company Information

Celgene Corporation
556 Morris Ave. Building S12
Summit, NJ 07901
(908) 673-9860
https://www.celgene.com
E-mail: Jordan.spadafora@twolabs.com

FEIN: 22-2711928
State of Formation: Delaware
Date Incorporated: 04/17/1986
File Number: 2088605

Ownership Information

Celgene Corporation is 100% owned by Bristol-Myers Squibb who is a Publicly Traded company on the NASDAQ stock exchange under the symbol BMY.

Bristol-Myers Squibb
430 E 29th Street 14th Floor
New York, NY 10016
(800) 332-2056
FEIN: 22-0790350

Officers

Phil Holzer- President
Business Address: 556 Morris Ave. Building S12. Summit, NJ 07901
Ownership %: 0%

Sophia Park- Vice President
Business Address: 556 Morris Ave. Building S12. Summit, NJ 07901
Ownership %: 0%

Katherine R. Kelly- Secretary
Business Address: 556 Morris Ave. Building S12. Summit, NJ 07901
Ownership %: 0%

Jeffrey Galik- Treasurer
Business Address: 556 Morris Ave. Building S12. Summit, NJ 07901
Ownership %: 0%

Designated Representative

Joseph Zielinski- Director of Drug Product Development Operations
Business Address: 556 Morris Ave. Building S12. Summit, NJ 07901
Ownership %: 0%

JOSEPH A. ZIELINSKI
[redacted]**UNION VALLEY ROAD**
MONROE TOWNSHIP, NEW JERSEY 08831
[redacted]

CAREER OBJECTIVE:

Dedicated, detail oriented and results driven individual seeking a senior managerial position in a growth-oriented company where my solid operations, compliance and systems development experience will be rewarded.

SUMMARY OF QUALIFICATIONS:

Highly motivated operations Director with over 23 years of experience. Strengths in serving as a strategic operational lead for Research and Clinical Manufacturing facilities, project management, Capital projects coordination and financial controls. Focus on developing and implementing lean, fit for purpose, sustainable operational systems for process area and facilities oversight. Partner with key internal and external stakeholders; build and develop high performing teams.

EMPLOYMENT EXPERIENCE:

Celgene Corporation, a Wholly-Owned Subsidiary of BRISTOL-MYERS SQUIBB,

Summit, NJ Director – Drug Product Development Operations, April 2017 - Present

- Responsible for the operational oversight, project management and business support activities for Celgene's internal Drug Product Development group, which includes the cGMP Process (Oral Solid Dose) Facility, Formulations Development (small molecule OSD and Parenteral) Facility, and Research Laboratory facilities.
- Provide strategic oversight for internal Drug Product Development Facilities build projects; coordinating scientific staff needs, oversight of Facility / Engineering / Qualification partners as well as design / construction firm activities.
- Provide guidance to ensure overall timeliness and compliance of project activities and deliverables; maintain spend within set financial project targets and communicating project status to Sr. Management, end-users and key stakeholders.
- Maintain strong comprehensive knowledge of, and manage direct staff which have responsibilities for the management and systems development / implementation for the following:
  - facility build / renovation project management; capital equipment project coordination and installations;
  - process engineering and equipment maintenance; commissioning / qualification and compliance activities;
  - procedural direction development, implementation and staff training;
  - equipment repair service and instrument calibration oversight;
  - budget development, metrics and reporting; materials and non-Capital equipment contracting and procurement
  - cGMP Quality System development and implementation for Process Facility and Warehouse Operations
  - facility / office planning and staff seating, facility maintenance and housekeeping; area security and access controls

Significant Accomplishments of Current Drug Product Development – Operations Director Role:

S6 Drug Product cGMP Facility:

- Assembled and executed the business plan which met the Global Pharmaceutical Development and Operations Division needs for establishing internal Oral Solid Dose manufacturing capabilities in support of early phase Clinical Trial Materials.
- Devised three phased approach developed and fund support of Initial Phase Operations (dispensing, milling / blending, encapsulation / check-weighing, bulk packaging); Enabled Phase Operations (spray drying, vacuum drying, roller compaction, high shear granulation / fluid bed drying, tablet compression and coating); and cGMP warehouse facility and procedural controls (materials receipt, documentation, internal routing, storage, shipment and waste)
- Established and implemented Quality systems for OSD Facility: design, utilization; utilities and equipment installations / qualifications; SOP's, Work Practices and staff training curriculums, cleaning verification; area monitoring and alarm responses; environmental monitoring and trending plan; audit support (for Corporate and Qualified Person inspections) of process facility and warehouse area.
- Completed Facility Initial Phase inspection - executed in period December 2017 (preliminary plan) to Sept 2019 (successful corporate audit completion) with release for manufacture fir US based Clinical programs.

S7 Potent Compound Handling Facility:

- Devised and presented business case to fund the build of internal OSD process facility specifically capable of handling potent / highly potent dry materials in contained unit operations.
- Collaborated with internal Environmental Health and Safety (EHS) leadership, external industry leaders and containment consultants to establish plan for facility design and equipment containment capable of processing to $\leq 0.1 mcg/m^3$.
- Oversight for the development of internal procedures and work practices to guide use of containment, in addition to personal protective equipment and respiratory protection devices
- Devised and implemented testing matrix strategy for installing, surrogate testing and reporting of containment performance results; ensuring periodic performance testing to verify maintenance of established containment targets.

CELGENE CORPORATION, Drug Product Development, Summit, NJ
Associate Director – Drug Product Development Operations, November 2014 – April 2017

- Devised and assembled the Celgene Small Molecule Drug Product Development Operations group.
- Assessed and initiated recruiting to fill key roles required to support group vision and remittance.
- Advanced and relocated the original Development Processing area from a 2400 ft^2 space which provided basic OSD formulations modalities, to a 10,000 ft^2 Facility which provides standard, enabled and parenteral development modalities.

MERCK & Co., MERCK RESEARCH LABORATORIES, Summit Formulation Sciences Facility, Summit, NJ (Formerly SCHERING-PLOUGH CORPORATION, Schering-Plough Research Institute, Oral and Specialty Product Development, Associate Director, Preclinical Development / Pilot Plant Lead, Building S7, September 2006 to November 2014

- Partnered in facility design and construction activities; started and managed the Summit Formulation Sciences Pilot Plant Manufacturing Facility which encompassed six key operational areas:
  Solid Dosage Development, Metered Dose Inhalation, Non-Sterile Liquids / Ointment / Cream Development, Dry-Powder Inhalation Development, Small Molecule Parenteral Development and Research Stability Areas
- Responsible for the daily operation of the pilot plant facilities, including scheduling and forecasting, resources planning, staff communications and trainings, facility and equipment maintenance activities, operational budget monitoring, safety and environmental coordination, project management, and support of formulations projects.
- Strong operational knowledge of oral solid dose manufacturing processes; such as high shear granulation, fluid bed drying and top-spray granulation, hot melt extrusion, roller compaction, spray drying, milling, blending, tableting and encapsulation.

SCHERING-PLOUGH CORPORATION, Kenilworth, New Jersey
TABLET MANUFACTURING MANAGER, November 2003 to September 2006

- Managed the Solid Dose Manufacturing Department encompassing granulation and tablet compression areas. Responsible for overall departmental operation and performance objectives, including product quality, GMP compliance, production, planning and scheduling, staff communication and training, safety and environmental compliance, operational and capital budgeting, and control of projects.
- Oversaw a supervisory staff of five employees, and an overall operating staff of 20 operator level employees.

SCHERING-PLOUGH CORPORATION, Kenilworth, New Jersey
PROJECT SUPERVISOR, SOLID DOSAGE PHARMACEUTICAL MANUFACTURING DEPARTMENT
June 2001 to November 2003

- Identified, developed and executed plans for departmental improvements relating to operation enhancements, compliance directives, facility upgrades and new equipment purchases. Generated and tracked annual Capital Budget and related Appropriations Requests for projects; monitored and reported on financial controls.

SCHERING-PLOUGH CORPORATION, Kenilworth, New Jersey
SUPERVISOR, SOLID DOSAGE PHARMACEUTICAL MANUFACTURING DEPARTMENT
April 1998 to June 2001

- Supervised granulation (wet and fluid bed), milling, blending and compression process involving all aspects of equipment operation, scheduling, troubleshooting, documentation and GMP regulation.
- Analyzed production problems and determined root cause. Implemented timely and appropriate corrective actions.

SCHERING-PLOUGH CORPORATION, Kenilworth, New Jersey
SUPERVISOR, TABLET AND AEROSOL PACKAGING DEPARTMENT
January 1997 to April 1998

- Provided direct supervision for 15 to 30 hourly employees operating various automated packaging equipment.
- Ensured department production schedule was maintained, scheduled daily work assignments and guided production.

CONSOLIDATED RAIL CORPORATION, Philadelphia Division, operating in North/Central New Jersey
TRAIN and ENGINE SERVICE, March 1996 to August 1996

KROBACK INC. / DANTE TUXEDOS, Linden, New Jersey
PRODUCTION MANAGER, Rental Garment Assembly Facility, June 1993 to March 1996

EDUCATION:
SETON HALL UNIVERSITY, Stillman School of Business, South Orange, New Jersey.
Bachelor of Science, Marketing, May 1993.

REFERENCES: Furnished upon request



Description of Operations

Celgene Corporation ("Celgene") is a Self-Distributing Self-Manufacturer of FDA-Approved prescription biopharmaceutical drugs for immunotherapy in cancer patients. Celgene's products are manufactured and distributed from their facility in Summit, NJ and will be shipped to various hospitals throughout the United States. Celgene's products are not controlled substances.

Manufacturing & Distribution Location
Celgene Corporation
556 Morris Ave. Building S12
Summit, NJ 07901
(908) 673-9860

FDA Registrations
FDA Establishment Identification Number: 3004991673
Expiration Date: 12/31/2021

Labeler Code:
59572

Celgene Corporation's hours of operation are 8:00am – 6:00pm EST, Monday through Friday

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through April 29, 2021

You have searched Finished drug products

Search Results: '59572'

Back to Search Page | Search Again

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Abecma	59572-515-01	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/2021	N/A	BLA	50 mL in 1 BAG (59572-515-01)
Abecma	59572-515-02	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/2021	N/A	BLA	250 mL in 1 BAG (59572-515-02)
Abecma	59572-515-03	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/2021	N/A	BLA	500 mL in 1 BAG (59572-515-03)
Idhifa	59572-710-30	100 mg/1	TABLET, FILM COATED	ORAL	NDA209606	Celgene Corporation	59572-710	enasidenib mesylate	ENASIDENIB MESYLATE	HUMAN PRESCRIPTION DRUG	08/01/2017	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (59572-710-30)
Idhifa	59572-705-30	50 mg/1	TABLET, FILM COATED	ORAL	NDA209606	Celgene Corporation	59572-705	enasidenib mesylate	ENASIDENIB MESYLATE	HUMAN PRESCRIPTION DRUG	08/01/2017	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (59572-705-30)

✓ verified M.H

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through April 22, 2021

You have searched Finished drug products

Search Results: *'59572'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Mark Date
Abecma	59572-515-01	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/
Abecma	59572-515-02	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/
Abecma	59572-515-03	300000000 1/mL	SUSPENSION	INTRAVENOUS	BLA125736	Celgene Corporation	59572-515	idecabtagene vicleucel	IDECABTAGENE VICLEUCEL	CELLULAR THERAPY	03/26/
Idhifa	59572-710-30	100 mg/1	TABLET, FILM COATED	ORAL	NDA209606	Celgene Corporation	59572-710	enasidenib mesylate	ENASIDENIB MESYLATE	HUMAN PRESCRIPTION DRUG	08/01/
Idhifa	59572-705-30	50 mg/1	TABLET, FILM COATED	ORAL	NDA209606	Celgene Corporation	59572-705	enasidenib mesylate	ENASIDENIB MESYLATE	HUMAN PRESCRIPTION DRUG	08/01/
Inrebic	59572-720-12	100 mg/1	CAPSULE	ORAL	NDA212327	Celgene Corporation	59572-720	Fedratinib Hydrochloride	FEDRATINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/16/
ISTODAX	59572-984-01		KIT		NDA022393	Celgene Corporation	59572-984	romidepsin		HUMAN PRESCRIPTION DRUG	01/04/
ONUREG	59572-730-07	200 mg/1	TABLET, FILM COATED	ORAL	NDA214120	Celgene Corporation	59572-730	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG	12/18/

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Mark Date
ONUREG	59572-740-07	300 mg/1	TABLET, FILM COATED	ORAL	NDA214120	Celgene Corporation	59572-740	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG	12/18/
ONUREG	59572-730-14	200 mg/1	TABLET, FILM COATED	ORAL	NDA214120	Celgene Corporation	59572-730	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG	09/01/
ONUREG	59572-740-14	300 mg/1	TABLET, FILM COATED	ORAL	NDA214120	Celgene Corporation	59572-740	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG	09/01/
OTEZLA	59572-630-27		KIT	ORAL	NDA205437	Celgene Corporation	59572-630	apremilast		HUMAN PRESCRIPTION DRUG	03/25/
OTEZLA	59572-630-99		KIT	ORAL	NDA205437	Celgene Corporation	59572-630	apremilast		HUMAN PRESCRIPTION DRUG	03/25/
OTEZLA	59572-631-06	30 mg/1	TABLET, FILM COATED	ORAL	NDA205437	Celgene Corporation	59572-631	apremilast	APREMILAST	HUMAN PRESCRIPTION DRUG	09/18/
OTEZLA	59572-631-28	30 mg/1	TABLET, FILM COATED	ORAL	NDA205437	Celgene Corporation	59572-631	apremilast	APREMILAST	HUMAN PRESCRIPTION DRUG	08/05/
OTEZLA	59572-632-55		KIT	ORAL	NDA205437	Celgene Corporation	59572-632	apremilast		HUMAN PRESCRIPTION DRUG	08/05/
Pomalyst	59572-504-21	4 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-504	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-501-00	1 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-501	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-503-00	3 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-503	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-502-21	2 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-502	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-501-21	1 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-501	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Mark Date
Pomalyst	59572-502-00	2 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-502	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-503-21	3 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-503	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Pomalyst	59572-504-00	4 mg/1	CAPSULE	ORAL	NDA204026	Celgene Corporation	59572-504	pomalidomide	POMALIDOMIDE	HUMAN PRESCRIPTION DRUG	02/18/
Reblozyl	59572-711-01	25 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	SUBCUTANEOUS	BLA761136	Celgene	59572-711	Luspatercept	LUSPATERCEPT	HUMAN PRESCRIPTION DRUG	11/08/
Reblozyl	59572-775-01	75 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	SUBCUTANEOUS	BLA761136	Celgene	59572-775	Luspatercept	LUSPATERCEPT	HUMAN PRESCRIPTION DRUG	11/08/
Revlimid	59572-410-00	10 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-410	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	12/27/
Revlimid	59572-415-00	15 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-415	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	07/07/
Revlimid	59572-425-00	25 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-425	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	07/07/
Revlimid	59572-415-21	15 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-415	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	07/07/
Revlimid	59572-402-28	2.5 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-402	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	05/09/
Revlimid	59572-420-00	20 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-420	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	06/10/
Revlimid	59572-402-00	2.5 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-402	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	05/09/

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Mark Date
Revlimid	59572-405-00	5 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-405	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	12/27/
Revlimid	59572-405-28	5 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-405	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	03/03/
Revlimid	59572-410-28	10 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-410	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	03/03/
Revlimid	59572-420-21	20 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-420	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	06/10/
Revlimid	59572-425-21	25 mg/1	CAPSULE	ORAL	NDA021880	Celgene Corporation	59572-425	Lenalidomide	LENALIDOMIDE	HUMAN PRESCRIPTION DRUG	03/03/
Thalomid	59572-205-94	50 mg/1	CAPSULE	ORAL	NDA020785	Celgene Corporation	59572-205	Thalidomide	THALIDOMIDE	HUMAN PRESCRIPTION DRUG	06/20/
Thalomid	59572-220-96	200 mg/1	CAPSULE	ORAL	NDA020785	Celgene Corporation	59572-220	Thalidomide	THALIDOMIDE	HUMAN PRESCRIPTION DRUG	06/20/
Thalomid	59572-210-95	100 mg/1	CAPSULE	ORAL	NDA020785	Celgene Corporation	59572-210	Thalidomide	THALIDOMIDE	HUMAN PRESCRIPTION DRUG	06/20/
Thalomid	59572-205-97	50 mg/1	CAPSULE	ORAL	NDA020785	Celgene Corporation	59572-205	Thalidomide	THALIDOMIDE	HUMAN PRESCRIPTION DRUG	01/26/
Thalomid	59572-215-93	150 mg/1	CAPSULE	ORAL	NDA020785	Celgene Corporation	59572-215	Thalidomide	THALIDOMIDE	HUMAN PRESCRIPTION DRUG	03/20/
VIDAZA	59572-102-01	100 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS; SUBCUTANEOUS	NDA050794	Celgene Corporation	59572-102	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG	07/05/

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Mark Date
ZEPOSIA	59572-810-07		KIT		NDA209899	Celgene Corporation	59572-810	ozanimod hydrochloride		HUMAN PRESCRIPTION DRUG	03/27/
ZEPOSIA	59572-810-97		KIT		NDA209899	Celgene Corporation	59572-810	ozanimod hydrochloride		HUMAN PRESCRIPTION DRUG	03/27/
ZEPOSIA	59572-820-30	.92 mg/1	CAPSULE	ORAL	NDA209899	Celgene Corporation	59572-820	ozanimod hydrochloride	OZANIMOD HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	03/27/
ZEPOSIA	59572-820-97	.92 mg/1	CAPSULE	ORAL	NDA209899	Celgene Corporation	59572-820	ozanimod hydrochloride	OZANIMOD HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	03/27/
ZEPOSIA	59572-890-91		KIT		NDA209899	Celgene Corporation	59572-890	ozanimod hydrochloride		HUMAN PRESCRIPTION DRUG	03/27/
ZEPOSIA	59572-890-97		KIT		NDA209899	Celgene Corporation	59572-890	ozanimod hydrochloride		HUMAN PRESCRIPTION DRUG	03/27/

Showing 1 to 50 of 50 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

ALABAMA
BOARD OF PHARMACY

Donna C. Yeatman, R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

MEMBERS 2020

Ralph Sorrell, R.Ph.
President

Brenda Denson, PharmD
Vice President

Chris Phung, R.Ph.
Treasurer

Robert Colburn, Jr., R.Ph.

Christy Garmon, PharmD.

August 28, 2020

To: CELGENE CORPORATION
86 MORRIS AVENUE
SUMMIT, NJ/07901

FROM: Wendy Passmore, Operations Manager
EMAIL- wpassmore@albop.com
FAX - 205-803-6481

RE: ADMINISTRATIVE HEARINGS

New Documents
Since March 2021
Appearance

CASE #: 20-L-0081

Your hearing is scheduled for **November 17, 2020** at **8:00 AM**

Please provide the following information.

NAME: _____

LICENSE/ REGISTRATION NUMBER _____ **PHONE #** (___)_____

ADDRESS: _____

_____

Please note: The administrative hearing will proceed as scheduled with or without your attendance.

☐ **I WILL NOT** be represented by an Attorney

☐ **I WILL** be represented by the Attorney listed below:

ATTORNEY'S NAME: _____ **PHONE #** _____

ADDRESS: _____

EMAIL _____

****

WHILE A CONTINUANCE IS NOT AUTOMATIC, ANY REQUEST FOR ONE MUST BE FILED AND RECEIVED BY THE BOARD'S HEARING OFFICER THIRTY (30) DAYS PRIOR TO YOUR SCHEDULED HEARING DATE.



2017

On July 27, 2017, Celgene Corporation agreed to pay $280 million to resolve allegations that is sold and promoted its drugs thalidomide (Thalomid) and lenalidomide (Revlimid) in violation of federal and state laws. The case was brought by a former Celgene sales representative, Beverly Brown, under the federal False Claims Act (FCA) and state analogues. The federal civil settlement agreement encompasses allegations that Celgene promoted Thalomid and Revlimid for off-label uses that were not approved by the FDA, were in many cases unsafe, and were not properly reimbursable by federal insurance programs. The suit also alleged that Celgene offered kickbacks in an effort to influence health care providers to select its products for use, regardless of whether they were reimbursable by federal or state health care programs or were medically necessary. Celgene said the litigation related primarily to allegations that Celgene promoted Thalomid for off-label uses before its 2006 FDA approval for newly diagnosed multiple myeloma. Under the settlement, Celgene paid a total of $280 million to the United States, 28 states, the District of Columbia, and the City of Chicago to resolve the litigation. Celgene noted that the Department of Justice and the other governmental entities declined to intervene in the litigation.

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
CELGENE CORPORATION	)	**BOARD OF PHARMACY**
Private Label Distributor Virtual Permit No. 194293	)	**CASE NO: 20-L-0081**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Celgene Corporation
86 Morris Avenue
Summit, New Jersey 07901

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on November 17, 2020 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Celgene Corporation (Celgene) as a Private Label Distributor-Virtual should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted based upon any or all of the following:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-32(a) and/or (f) by engaging in the distribution of prescription drugs into this State during 2020 without a valid or current permit to do so.

The Board alleges that each instance of the above described conduct is a separate and distinct violation.

Notice is further given that in the event you are found guilty of the allegations contained in any or all of the preceding Counts contained in this Statement of Charges and Notice of Hearing, the Board may consider in assessing punishment the Consent Order entered by the Board on September 17, 2015, said document being attached hereto and made a part hereof as Exhibit "A".

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 11th day of August, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT A

IN THE MATTER OF:	)	**BEFORE THE ALABAMA**
	)	
CELGENE CORPORATION	)	**STATE BOARD OF PHARMACY**
	)	
Manufacturer/Wholesaler/ Distributor Permit No. 194293	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Celgene Corporation (hereinafter referred to as "CELGENE") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that CELGENE violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. CELGENE shall pay to the Board an administrative fine in the amount of Five Hundred dollars ($500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and CELGENE shall not attempt to discharge the same in any bankruptcy proceeding.

3. That CELGENE expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. CELGENE further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, CELGENE hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That CELGENE agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That CELGENE acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. CELGENE acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 10th day of September, 2015.

Celgene Corporation

By: _____
Its: _____

_____
Sharon Stuart, Attorney for Celgene Corporation

DONE this the 17 day of Sept, 2015.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Dan McConaghy, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

ALABAMA STATE BOARD OF PHARMACY

SCHEDULING ORDER

In order to administer the matter, set for hearing in a manner fair to the Respondent and the Alabama State Board of Pharmacy and consistent with the interest in completing this matter in the shortest possible time, this Order is issued. Read carefully; failure to comply with the below listed requirements may result in sanctions.

IT IS ORDERED that the Respondent and the Board are directed to comply with each of the following directives:

(1) DISCOVERY

All Requests for Production and other discovery requests must be submitted to be received by the Administrative Hearing Officer and a copy to the Board's counsel or Respondent's counsel if request by the Board, no later than forty (40) days before the scheduled hearing at:

Vance L. Alexander
Administrative Hearing Officer
Alabama Board of Pharmacy
Post Office Box 380684
Birmingham, Alabama 35238-0684
E-mail: vlalex@bellsouth.net

With a copy to the Respondent and Board's Counsel

James S. Ward, Esquire
Ward & Cooper, LLC
2100 South Bridge Parkway
Suite 645
Birmingham, Alabama 35209
E-mail: jward@wardcooperlaw.com

(2) REQUESTS FOR CONTINUANCE

All requests for continuances of the matter shall be submitted to be received by the Administrative Hearing Officer no later than thirty (30) days before the scheduled hearing with a copy to the Board's counsel or Respondent and if not, unless there are emergency circumstances, the hearing WILL NOT be continued.

(3) PLEADINGS

All other pleadings shall be submitted to be received by the Administrative Hearing Officer no later than fifteen (15) days before the scheduled hearing with a copy to the Board's counsel or Respondent if submitted by the Board. Pleadings shall be submitted with the style, case number and containing a certificate of service.

(4) CONSENT ORDER/SETTLEMENT PROPOSALS

If you are interested in a settled proposal from the Board, you must inform Board's counsel seven days in advance of the Board meeting in the month prior to the scheduled hearing. For the attached Statement of Charges and Notice of Hearing the prior Board meeting is 10-14-20. Unless emergency circumstances exist, proposals submitted after the above date will not be considered.

(5) COPIES

Prior to the hearing the parties shall prepare a sufficient number of copies of documents which are proposed to be introduced into evidence at the administrative hearing. With the exception of the Statement of Charges and Notice of Hearing, documents which are proposed to be introduced into evidence at the administrative hearing shall not be presented to the Administrative Hearing Officer prior to the hearing unless otherwise ordered.

(7) REPRESENTATION

Individuals may represent themselves before the Board. Legal entities such as corporations, LLCs and partnerships must be represented by an attorney licensed to practice in the State of Alabama. Attorneys representing Respondents in administrative hearings before the Board shall file a Notice of Appearance with the Administrative Hearing Officer with a copy to the Board's counsel. Attorney should compare their calendar to the scheduled hearing date before accepting representation to avoid conflict. In the event, an attorney who is not a member of the Alabama Bar, is representing a Respondent in a matter to be heard in an administrative hearing, the attorney shall make Application for Admission Pro Hac Vice To Practice Under Rule VII of The Rules Governing Admission To The Alabama State Bar.

DONE and ORDERED this the 28 day of July, 2020.

Vance L. Alexander

VANCE L. ALEXANDER
ADMINISTRATIVE HEARING OFFICER

Copies to:
Respondent
Mr. James S. Ward, Esq.
Ms. Wendy Passmore, Alabama Board of Pharmacy

AL 2015

IN THE MATTER OF:	)	**BEFORE THE ALABAMA**
	)	
CELGENE CORPORATION	)	**STATE BOARD OF PHARMACY**
	)	
Manufacturer/Wholesaler/ Distributor Permit No. 194293	)	
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Celgene Corporation (hereinafter referred to as "CELGENE") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that CELGENE violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. CELGENE shall pay to the Board an administrative fine in the amount of Five Hundred dollars ($500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and CELGENE shall not attempt to discharge the same in any bankruptcy proceeding.

3. That CELGENE expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. CELGENE further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, CELGENE hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That CELGENE agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That CELGENE acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. CELGENE acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 10th day of September, 2015.

Celgene Corporation

By: _____
Its: Sr. Analyst

_____
Sharon Stuart, Attorney for Celgene Corporation

DONE this the 17 day of Sept, 2015.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Dan McConaghy, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & WILSON, LLC.
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

MD 2014

IN THE MATTER OF	*	**BEFORE THE**
CELGENE CORPORATION	*	**MARYLAND STATE**
PERMIT NO. D02255	*	**BOARD OF PHARMACY**
	*	

* * * * * * * * * * * *

CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") was advised by State License Servicing, LLC, on behalf of by Celgene Corporation, a wholesale drug distributor licensed in Maryland under Permit No D02255, that Celgene had been disciplined by the Maine Board of Pharmacy on May 17, 2013, for failing to disclose disciplinary action taken against Celgene by the Oregon Board of Pharmacy on July 17, 2008. Upon receiving this information, the Board reviewed previous applications filed by Celgene and determined that Celgene also did not previously disclose the Oregon disciplinary action to the Board.

In lieu of instituting formal proceedings against Celgene, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Celgene have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. On or about June 2013, the Board received credible information from State License Services, on behalf of Celgene Corporation, that Celgene had been disciplined by the Maine Board of Pharmacy on May 17, 2013, for failing to disclose prior discipline it received from the Oregon Board of Pharmacy in 2008. The Maine Board issued a Warning, and a civil penalty of $500 against Celgene.

2. The Oregon Board of Pharmacy entered into a Consent Order with Celgene Corporation on July 17, 2008, based on Celgene's unauthorized distribution of drugs into Oregon without duly registering as a drug outlet. The Oregon Board issued a civil penalty against Celgene in the amount of $500.
3. Upon receipt of the above information, the Board reviewed the renewal application filed by Celgene Corporation on December 29, 2008. Based on the Board's review, it determined that Celgene failed to disclose the disciplinary action taken against it by the Oregon Board of Pharmacy in July 2008.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Celgene Corporation, is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-6C-11 and COMAR 10.34.22.05A(3) and (4).

ORDER

Based upon an affirmative vote of a majority of the Board under the authority of Md. Code Ann., Health Occ. § 12-6C-11 and COMAR 10.34.22.05, it this 30th day of May, 2014, hereby,

ORDERED that Celgene Corporation, Permit No. D02255, shall pay a FINE in the amount of $500.00, payable to the Maryland Board of Pharmacy within ninety (90) days of the date of this Order; and be it further,

ORDERED that Celgene Corporation shall comply with all laws and regulations governing the wholesale distribution of prescription drugs and devices into, out of, and within the State of Maryland; and be it further,

ORDERED that in the event that Celgene Corporation violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension, revocation, and fines, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., State Gov't § 10-611 *et seq.* (2004).

May 30, 2014
Date

LaVerne G. Naesea
Executive Director for:

Lenna Israbian-Jamgochian, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Celgene Corporation submits to the foregoing Consent Order as a resolution of this matter and agree to be bound by its terms and conditions.

2. Celgene Corporation acknowledges the validity of this Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Celgene Corporation acknowledges that, by entering into this Consent Order, Celgene Corporation is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Celgene Corporation acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

5. Celgene Corporation signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Celgene Corporation fully understands the language, meaning, and effect of this Consent Order.

5/20/14
Date

Name: William J. Streu
Title: Assoc. Dir. Sr. M. Compl. Analyst

STATE OF ILLINOIS
COUNTY/CITY OF Cook:

I hereby certify that on this 20th day of MAY, 2014, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared William J. Streu, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Celgene Corporation.

Official Seal
Diane M. DiPrizio
Notary Public State of Illinois
My Commission Expires 03/25/2017

Diane M DiPrizio
Notary Public
My commission expires: 3/25/2017

MI 2014

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

CELGENE CORPORATION
License Number: 53-06-002659

File Number: 53-13-129653
CONSENT ORDER AND STIPULATION

CONSENT ORDER

An Administrative Complaint, hereafter Complaint, was issued on December 19, 2013, charging Celgene Corporation, hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

Respondent Wholesaler has admitted, by Stipulation submitted herewith, that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code; and

The Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, has reviewed the Stipulation, and based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now therefore,

IT IS FOUND that the facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs**, hereafter Department, **Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display the file number **53-13-129653**.

IT IS FURTHER ORDERED that in the event Respondent Wholesaler violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 4/9/14

MICHIGAN BOARD OF PHARMACY

By: _____

Chairperson, Disciplinary Subcommittee

CONTINUED ON NEXT PAGE

STIPULATION

1. The facts alleged in the Complaint dated December 19, 2013, are true and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

2. Respondent Wholesaler understands and intends that by signing this Stipulation Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to the charges.

3. Patti Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

4. This Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

5. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 2-24-14

AGREED TO BY:

Donald Bundschuh
Authorized Representative for
Celgene Corporation
Respondent Wholesaler

Dated: 18-FEB-2014

This is the final page of a Consent Order and Stipulation in the matter of Celgene Corporation, File Number 53-13-129653, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included.

WH

ME 2013

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
COMPLAINTS AND INVESTIGATION
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Paul R. LePage
Governor

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

May 28, 2013

Celgene Corporation
Attn: Joanna Futyna
7339 Industrial Blvd
Allentown, PA 18106-9369

Re: 2012 PHA 8751

Dear Ms. Futyna:

Please find enclosed a copy of the fully-executed consent agreement made by you, the Board of Pharmacy, and the Department of Attorney General in this matter.

As all conditions of the Consent Agreement have been met; the above-mentioned complaint file is now closed.

If you have any questions, please feel free to contact this office.

Sincerely,

Kelly L. McLaughlin
Senior Consumer Assistant Specialist
(email:kelly.l.mclaughlin@maine.gov)

Enclosure

cc: Michael Miller, Assistant Attorney General
Geraldine L. Betts, Board Administrator
Thomas Avery, Chief Field Investigator
Jeffrey Frankel, OPOR Staff Attorney

STATE OF MAINE
BOARD OF PHARMACY

In re:	)	CONSENT
Celgene Corporation	)	AGREEMENT
Complaint No. 2012-PHA-8751	)	

PARTIES

This document is a Consent Agreement ("the Consent Agreement") regarding disciplinary action against the Wholesaler license for Celgene Corporation ("Celgene"). The parties to the Consent Agreement are: Celgene; the Maine Board of Pharmacy ("the Board"); and the State of Maine Office of Attorney General ("the Attorney General"). The Consent Agreement is entered into pursuant to 10 M.R.S § 8003(5-A)(C).

STATEMENT OF FACTS

1. At all times relevant to this agreement, Celgene was licensed by the Board as a wholesaler, license no. WH70001425.

2. On or about July 17, 2008, Celgene was disciplined by the Oregon Board of Pharmacy. The discipline was in the form of a consent order and involved payment of a civil penalty in the amount of $500.00.

3. On its December 15, 2008 application for renewal of its wholesaler license, Celgene unintentionally failed to disclose the above-mentioned Oregon discipline. .

CONCLUSIONS OF LAW

4. Celgene, as a wholesaler license applicant in the State of Maine, is subject to 32 M.R.S. § 13742-A(1) and 10 M.R.S. § 8003(5-A).

5. Failure by a wholesaler license applicant to disclose disciplinary actions taken against them by other state Boards of Pharmacy is a violation of 10 M.R.S. § 8003(5-A)(A)(1), and such violation constitutes grounds for discipline.

TERMS OF CONSENT AGREEMENT

6. At its meeting on April 4, 2013, the Board reviewed the above mentioned information. Based on this information, the Board voted to offer Celgene this Consent Agreement. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Senior Consumer Assistant

Specialist, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333 by May 7, 2013, the Board will resolve this matter with an adjudicatory hearing

7. As a condition of licensure and for conduct described in paragraph 5 above, Celgene agrees to the following:

A. A WARNING; and

B. Payment a CIVIL PENALTY in the amount of five hundred dollars ($500.00).

8. The Attorney General and the Board agree that no further agency or legal action will be taken against Celgene's license based on the specific violations admitted to herein, except in the event that Celgene does not comply fully with the terms of the Consent Agreement. Any violation of the Consent Agreement will be a ground for discipline by the Board.

9. The Consent Agreement is not subject to appeal.

10. The Consent Agreement is not subject to amendment except by written agreement of all parties.

11. The Consent Agreement is a public document within the meaning of 1 M.R.S. § 402, et seq.

12. Celgene understands that the execution of the Consent Agreement is completely voluntary and that it has the right to consult with an attorney before signing the Consent Agreement.

4A

13. Celgene acknowledges by signature hereto of an authorized representative that it has read this Consent Agreement, that is has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

For Celgene Corporation:

Dated: 30 APRIL 2013

Signature of Authorized Representative

Jeff S. Iverman, Corp VP Technical Operations, Americas
Print Name and Title

Dated: 5/14/13

JOSEPH BRUNO, R.Ph., PRESIDENT
Board of Pharmacy

Dated: 5-17-13

CARRIE L. CARNEY
Assistant Attorney General

OR 2008

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 2007-0136
	)	
CELGENE CORPORATION	)	CONSENT ORDER
	)	
Respondent	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Civil Penalty; Answer Required ("Notice") regarding the Respondent in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the Respondent as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the Respondent is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the Respondent admits that the facts alleged in the above-noted Notice are true, that the Respondents conduct, as admitted, violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.335, 689.405, and 689.445 for disciplinary action by the Board; and

WHEREAS, the Respondent consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The Respondent shall pay a civil penalty to the Board in the amount of $500, said payment to be made within ten days from the effective date of this Consent Order.

2. Respondent shall obtain proper registration with the Board as a Wholesaler Class I Wholesaler.

3. This Consent Order shall become effective immediately upon issuance by the Board.

4. In the event that the Respondent fails to timely pay the civil penalty as ordered herein, the Board may take further action, after notice and hearing.

CONSENT

I hereby acknowledge that I am the authorized representative of Respondent. On behalf of the Respondent, I further certify that I have read and understand the Notice and this Consent Order and am aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Boards final order. On behalf of the Respondent I agree to the Board entering the Consent Order.

RPh — 4/1/08

Authorized Representative — Date
CELGENE CORPORATION
Respondent

Legal Dept
4/11/08

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

7/17/08

Gary Miner, R.Ph., — Date
Compliance Director

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107308364

Application/License No. _____

Celgene Corporation, doing or intending to do business
(Applicant/Principal)
as a pharmaceutical wholesaler, whose address for purposes of service is
556 Morris Ave, Bldg S12, Summit, NJ 07901, as
(Address of Applicant/Principal)
PRINCIPAL, and Travelers Casualty and Surety Company of America, a
(Surety Company)
corporation organized under the laws of the state of CT
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Tower Square , Hartford, CT 06183 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 22, 2021.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of January, 2021.

APPLICANT/PRINCIPAL
Celgene Corporation

By: _____
Authorized Representative

SURETY COMPANY
Travelers Casualty and Surety Company of America

By: _____
Surety Company's Representative

Joshua Sanford, Attorney-in-fact
print name

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD, CONN.

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Donna M Planeta

_____
Witness Eric Strba

Countersigned by:

_____
Nevada Resident Agent Aimee R Perondine
NV Non-Resident Agent License No. 3134182

TRAVELERS	**Travelers Casualty and Surety Company of America** **Travelers Casualty and Surety Company** **St. Paul Fire and Marine Insurance Company** **Farmington Casualty Company**

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Joshua Sanford** of **Short Hills, NJ** , their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law, including the following bond:

Surety Bond No.: 107308364
OR
Project Description: NV Pharmaceutical Wholesaler Bond

Principal: Celgene Corporation
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **6th** day of **May, 2019.**

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **6th** day of **May, 2019**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 22nd day of January, 2021.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which this Power of Attorney is attached.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-01136

BRISTOL-MYERS SQUIBB COMPANY
(Exact name of registrant as specified in its charter)

Delaware	22-0790350
(State or other jurisdiction of incorporation or organization)	(I.R.S Employer Identification No.)

430 E. 29th Street, 14FL, New York, NY 10016
(Address of principal executive offices)

(212) 546-4000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.10 Par Value	BMY	New York Stock Exchange
1.000% Notes due 2025	BMY25	New York Stock Exchange
1.750% Notes due 2035	BMY35	New York Stock Exchange
Celgene Contingent Value Rights	CELG RT	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

Title of each class
$2 Convertible Preferred Stock, $1 Par Value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the 2,252,423,640 shares of voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $132,442,510,032. Bristol-Myers Squibb has no non-voting common equity. At February 1, 2021, there were 2,240,475,153 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of the definitive proxy statement for the registrant's Annual Meeting of Shareholders to be filed within 120 days after the conclusion of the registrant's fiscal year ended December 31, 2020 with the U.S. Securities and Exchange Commission pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent described therein.

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☑ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Dexcom, Inc.

Physical Address: 6340 Sequence Drive

City: San Diego State: California Zip Code 92121

Telephone Number: 858-200-0200 Fax Number: 858-333-8210

Toll Free Number: 888-738-3646

E-mail: QUALITYCOMPLIANCE@DEXCOM.COM Website: www.dexcom.com

Facility Manager: Coral Mengual Sooy

Professional qualifications and experience of facility manager: See resume.

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☑ Practitioners ☑ Hospitals ☑ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☑ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A - DEXCOM ONLY DISTRIBUTES DEXCOM DEVICES - NO OTHERS
Address:

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: NV20061678547

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Katrina Morgera

Print Name of Authorized Person

4/27/2021

Date

Board Use Only	Date Processed: 6/15/2021	Amount: 500 check # 0100012474

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: DELAWARE

Parent Company if any: N/A

Corporation Name: DEXCOM, INC.

Mailing Address: 6340 SEQUENCE DR

City: SAN DIEGO State: CA Zip: 92121

Telephone: 858-200-0200 Fax: 858-333-8210

Contact Person: MELISSA RUSSELL - COMPLIANCE SPECIALIST

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 5/13/1999

Registration number issued: 000-51222

Stock Exchange: DXCM

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: NV20061678547

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors. ATTACHED

OSP 07 102308

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

DEVICE MANUFACTURING LICENSE

DexCom Incorporated
6340 Sequence Drive 6290 Sequence Drive
6350 Sequence Drive 5985 Pacific Center Boulevard
San Diego, CA 92121

LICENSE NUMBER: 47936
EXPIRATION DATE: 8/15/2021

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 8/27/2019

1037

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DEXCOM, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DEXCOM, INC." WAS INCORPORATED ON THE THIRTEENTH DAY OF MAY, A.D. 1999.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3030192 8300

SR# 20210511423

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202540670

Date: 02-18-21

OFFICERS and BOARD MEMBERS

OFFICERS

Name	Title	Business Address
Kevin R. Sayer	President & CEO	6340 Sequence Drive San Diego, CA 92121-4356
Quentin Blackford	CFO & COO	6340 Sequence Drive San Diego, CA 92121-4356
Donald Abbey	EVP Quality and Regulatory Affairs	6340 Sequence Drive San Diego, CA 92121-4356

BOARD MEMBERS

Kevin Sayer	Executive Chairman	6340 Sequence Drive San Diego, CA 92121-4356
Steven Altman	Director	6340 Sequence Drive San Diego, CA 92121-4356
Nicolas Augustinos	Director	6340 Sequence Drive San Diego, CA 92121-4356
Richard Collins	Director	6340 Sequence Drive San Diego, CA 92121-4356
Mark Foletta	Director	6340 Sequence Drive San Diego, CA 92121-4356
Barbara Kahn	Director	6340 Sequence Drive San Diego, CA 92121-4356
Jay Skyler	Director	6340 Sequence Drive San Diego, CA 92121-4356
Eric Topol	Director	6340 Sequence Drive San Diego, CA 92121-4356
Karen Dahut	Director	6340 Sequence Drive San Diego, CA 92121-4356
Bridgette Heller	Director	6340 Sequence Drive San Diego, CA 92121-4356
Kyle Maladay	Director	6340 Sequence Drive San Diego, CA 92121-4356

MANAGING EMPLOYEE

Jereme Sylvain	SVP Finance & Chief Accounting Officer	6340 Sequence Drive San Diego, CA 92121-4356

CORAL MENGUAL-SOOY, CSCP

LinkedIn: http://www.linkedin.com/pub/coral-sooy/8a/866/287/
[redacted]

SIGNIFICANT ACHIEVEMENTS

- Increased capacity within the existing facility by 18.7% or 700 pallet positions to support the relocation of $13MM of ambient, refrigerated (2C°-8C°) and frozen (-20C°; -80C°) materials from a third part facility.
- Improved performance in put-away times from 44% of materials put-away in 24 hrs to 95.6% and maintained this consistently by implementing dock scheduling.
- Collaborated with cross-functional team from manufacturing site and sales to reduce errors that were delaying the receipt of materials by 21%.
- Implemented mobile computing units to perform transactions live at the location during the receipt and inventory movement process, driving a receiving accuracy performance of 99.6%.
- Developed reporting on SKUs in Control Limits, exposing $10.2MM of at-risk inventory due to dating or time in stock; collaborated with planners across different business units to raise awareness to the issue and drive improvements in performance.
- Established JIT replenishment process for non-inventory supplies by creating min, max, and reorder points based on forecasted daily usage and order lead times, reducing supplies by 73%.

PROFESSIONAL EXPERIENCE

Senior Manager Materials, Dexcom Inc. **2020-Present**

- Responsible for day-to-day operations of receiving and distribution of medical devices.

Warehouse Manager, Abbott Inc. **2013-2020**

- Led a team of 35+ associates (Receiving, Transportation, Inventory Control, Purchasing, EH&S, Facilities, HR) to achieve excellence in warehousing and distribution of raw materials and finished goods. Supported the delivery of over 5.8MM units and the receipt of over 25M pallets annually.
- Directed 3 different warehouses within San Diego, totaling 120M sqft and 5,350 pallet positions.
- Managed annual inventory value of $330M with 99.9% financial accuracy and bin accuracy of 98.9%.
- Ensured compliance to local and federal guidelines with no major external audit findings acting as the primary contact regarding Dangerous Goods Shipping, Hazardous Material Storage, Air Pollution Control, OSHA, Fire/Building Safety, FM Global, and C-TPAT. Provided support for other site programs including TSA CCSP, ISO, and FDA.
- Established relevant metrics and reporting methodologies to drive operational excellence around quality, people, customer, and cost including accuracy, recordable cases, near misses, cross-training commitment, SKUs in control limits, on time material receipt, on time order fulfillment to manufacturing, supplier delivery performance, UPPH, and OT.
- Managed the preventative maintenance program of 278+ assets to reduce downtime and repair costs; performed initial equipment assessment to establish PM schedules, operating and safety instructions for all equipment.
- Oversaw renovations at a 105M sf facility comprised of office, lab, and warehouse space including flood restoration, office remodels, rebranding, racking installations, freezer installations, sprinkler system upgrades, and security system upgrades.
- Implemented programs to ensure a safe working environment including the establishment of a Safety Committee, near miss reporting, safety training, and daily safety audits leading to the site achieving over 7 years without a workplace injury.
- Created programs to maintain a highly engaged workforce during a period of rapid change, leading to a 18.21% improvement in engagement as measure through a quarterly employee feedback survey.

CORAL MENGUAL-SOOY, CSCP

LinkedIn: http://www.linkedin.com/pub/coral-sooy/8a/866/287/
[redacted]

- Established a robust cross training program with over 200 goals annually and 90%+ completion adherence.
- Supported the receipt of over 25M pallets of raw material and finished goods annually with 99.3% receipt accuracy.
- Managed non-inventory purchases of $1.6MM annually within budget for the site.

Account Manager, Sol Pacific, LLC **2009-2013**

- Maintained and audited all employee paperwork including training records, I-9 forms, W-2 forms, and other certifications to ensure compliance to local, state, and federal regulations.
- Improved efficiency in record location process by establishing an maintaining an organization system for vendor, clientele, and employee information.
- Performed data entry for accounts payable and accounts receivable activities; followed-up with customers as needed to determine payment status.
- Increased customer satisfaction and retention by improving communication with the customer-including weekly check-ins, as well as a 24 hour response time to all email and telephone service requests.

EDUCATION & PROFESSIONAL DEVELOPMENT

Bachelors of Science in Management Science, 2012
University of California, San Diego
Certified Supply Chain Professional (CSCP), 2014
APICS
DOT & IATA Dangerous Good Regulation, 2019
GSI Training Services, Inc

COMPUTER PROFICIENCIES

SAP, JDE, Agile, Ensur, MS Office, MAXIMO, ManagerPlus

Help (./help/index.html)

DRLM Home (mainMenu.htm) > Change, Deactivate, or Reactivate Listings

Listing Information

Listing Number	Premarket Submission Number	View Proprietary Names and Labeling
D360539	K191833	View All

Product Information

Medical Specialty	Product Code	Device/Product Name	Class	Submission Type
CH	QII	Integrated continuous glucose monitoring system for professional directed retrospective or real-time use	2	510(k)

Establishment Information

Registration Number	Name	Address	Status	Activities
3004753838	DEXCOM, INC.	6340 Sequence Dr, SAN DIEGO, California, 92121, UNITED STATES	Active	Manufacturer
3013435121	Dexcom, Inc.	232 South Dobson Road, Mesa, Arizona, 85202, UNITED STATES	Active	Manufacturer

Previous (drlm.htm?_flowExecutionKey=_c6DAC727E-90AE-0389-704C-BD62DFF103CE_kF4718F96-DAC2-F5E1-A375-2C698C7E193C8&_eventId=back)

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
DEXCOM, INC.
6340 Sequence Dr
SAN DIEGO , CA 92121
Registration Number: 3004753838
FEI Number*: 3004753838
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
DEXCOM, INC.
6340 Sequence Drive
San Diego, CA US 92121
Owner/Operator Number: 9071756

Official Correspondent:
Anita Rees
6340 Sequence Drive
San Diego, CA 92121
Phone: 858-2000203

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 04/26/2021
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended **December 31, 2020**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 000-51222

dxcm-20201231_g1.jpg

DEXCOM, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0857544**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6340 Sequence Drive, San Diego, CA 92121
(Address of principal executive offices)

(858) 200-0200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 Par Value Per Share	DXCM	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,7,8

☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6 ☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: G1 Therapeutics, Inc.

Physical Address: 700 Park Offices Drive, Suite 200, P.O. Box 110341

City: Research Triangle Park State: NC Zip Code: 27709

Telephone Number: (919) 213 - 9835 Fax Number: N/A

Toll Free Number: _____

E-mail: licensing@g1therapeutics.com Website: https://www.g1therapeutics.com/

Facility Manager: James Stillman Hanson

Professional qualifications and experience of facility manager:

See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies x Practitioners ☒ Hospitals ☐ Wholesalers

☐ Other: Specialty Distributors, Specialty Pharmacies

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices

☐ Poisons or Chemicals

☐ Controlled Substances (include copy of DEA)

☐ Other: _____

☐ Hypodermic Devices

☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

James Stillman Hanson
Print Name of Authorized Person

5/12/2021
Date

Board Use Only Date Processed: 5/25/2021 ✓ Amount: 500 Check # 13565

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: N/A

Corporation Name: G1 Therapeutics, Inc.

Mailing Address: 700 Park Offces Drive, Suite 200, P. O. Box 110341

City: Research Triangle Park State: NC Zip: 27709

Telephone: (919) 213 - 9835 Fax: N/A

Contact Person: James Stillman Hanson

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 05/19/2008

Registration number issued: 4549681

Stock Exchange: GTHX

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number:

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

1050

2021

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
1686

LICENSE/CERTIFICATE: Virtual Manufacturer
TYPE

Expiration Date 12/31/2021

LICENSEE OR CERTIFICATOR

G1 Therapeutics, Inc.
700 Park Offices Drive, Suite 200
Research Triangle Park NC 27709

LICENSED 2021 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

STEVE TROXLER, COMMISSIONER

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: G1 Therapeutics, Inc.

Address: 700 Park Offices Drive, Suite 200 Research Triangle Park, NC 27709

License Type: Virtual Manufacturer

License Number: 1686

Status: Active - in good standing

Issue Date: 3/3/2021

Original Issue: 3/3/2021

Expiration Date: 12/31/2021

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "G1 THERAPEUTICS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "G1 THERAPEUTICS, INC." WAS INCORPORATED ON THE NINETEENTH DAY OF MAY, A.D. 2008.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4549681 8300

SR# 20211236611

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202931823

Date: 04-09-21

Description of Operations

G1 Therapeutics, Inc. is a VirtualManufacturer. G1 Therapeutics, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors by their Third-Party Logistics Provider, Integrated Commercialization Solutions, LLC , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:

We are using the following contract manufacturer to produce our product:

Patheon
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
FDA Establishment Number: 1018495

Patheon manufactures G1 Therapeutics, Inc.'s product and packages finished product. At no time does Patheon own the product, contract with G1 Therapeutics, Inc.'s customers, invoice, nor sell a G1 Therapeutics, Inc. product. G1 Therapeutics, Inc.'s products are not Controlled Substances.

Labeler Code:
73462

Product:
Trilaciclib

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC acts as G1 Therapeutics, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of G1 Therapeutics, Inc.'s product to Specialty Distributors throughout the United States. Integrated Commercialization Solutions, LLC's address is:

Integrated Commercialization Solutions, LLC
420 International Blvd,
Brooks, KY 40109

G1 Therapeutics, Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through May 25, 2021

You have searched Finished drug products

Search Results: '73462'

Back to Search Page | Search Again

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Cosela	73462-101-01	300 mg/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA214200	G1 Therapeutics, Inc.	73462-101	trilaciclib	TRILACICLIB DIHYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/12/2021	N/A	NDA	1 VIAL, GLASS in 1 CARTON (73462-101-01) > 20 mL in 1 VIAL, GLASS

Showing 1 to 1 of 1 entries

Previous 1 Next

Verified M.H 5/25/21

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through April 12, 2021

You have searched Finished drug products

Search Results: *'73462'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name
Cosela	73462-101-01	300 mg/20mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA214200	G1 Therapeutics, Inc.	73462-101	trilaciclib	TRILACICLIB DIHYDROCHLORIDE	HUMAN PRESCRIPTIC DRUG

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Ownership Information

G1 Therapeutics, Inc.
700 Park Offices Drive
Suite 200
Research Triangle Park, NC 27709
(919)213-9835
licensing@g1therapeutics.com

FEIN: 26-3648180
State of Formation: DE
Date Incorporated: 5/19/2008
File Number: 4549681

G1 Therapeutic, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol GTHX.

Officers

John Bailey, Jr., Chief Executive Officer and President

Mark Avagliano, Chief Business Officer

Terry Murdock, Chief Operating Officer

Rajesh Malik, Chief Medical Officer and Senior Vice President, R&D

James Stillman Hanson, General Counsel and Corporate Secretary

Jennifer Moses, Chief Financial Officer

James Stillman Hanson
Office: 919-907-1915; Cell: [redacted]
shanson@g1therapeutics.com

QUALIFICATION SUMMARY

Trusted advisor to public and private companies for over 18 years. Business-oriented and practical corporate attorney with management and transactional experience. Responsible for the successful execution of corporate transactions, including public offerings, financings, partnerships, mergers and acquisitions, totaling over $30 billion in aggregate value. Possess extensive expertise in corporate governance, securities law, mergers and acquisitions, equity and debt financings, complex commercial transactions, executive compensation, compliance, employment issues, litigation and investigations.

EDUCATION

University of North Carolina School of Law, Chapel Hill, NC
Juris Doctor with Honors, May 2001

Wake Forest University, Winston-Salem, NC
Bachelor of Arts in Economics and with Honors in History, May 1994

PROFESSIONAL EXPERIENCE

G1 Therapeutics, Inc., RTP, NC — ***General Counsel, June 2018 – Present***

- Leads and manages the legal function to ensure business objectives are met
- Serves as chief adviser and strategic business partner to the chief executive officer, executive leadership team, and the Board of Directors on all legal, corporate governance, and compliance matters
- Serves as corporate secretary and chief compliance officer
- Supports business operations and provides direction and counsel regarding compliance with all applicable laws and regulations, and staying abreast of laws, legislative developments and developing external trends
- Collaborates with human resources on executive compensation, benefits and employment law matters to ensure statutory and regulatory compliance
- Advises on due diligence, documentation and other processes with respect to potential mergers, acquisitions, licenses and other strategic initiatives (including those relating to intellectual property) as well as supervising outside counsel
- Manages all litigation, legal claims and disputes
- Evaluates, selects and manages outside legal counsel and expert advisers as needed, and coordinates delivery of legal services to internal business partners

IQVIA Holdings Inc., Durham, NC — ***Associate General Counsel, November 2010 – May 2018***

Vice President, Corporate Governance

- Led the Quintiles legal team in the merger with IMS Health, an approximately $20 billion transaction
- Managed outside counsel in the refinancing transactions immediately after the merger, consisting of $6.9 billion in total debt refinancing activities
- Led legal team in the multiple secondary offerings over $3.3 billion in 2017
- Led legal team in the share repurchase transaction totaling $750 million
- Managed outside counsel in the sale of €1,425 million Euro Notes
- Supported the Board of Directors and the Audit and Compensation Committees

James Stillman Hanson
Office: 919-907-1915; Cell: [redacted]
shanson@g1therapeutics.com

- Negotiated mergers and acquisitions agreements
- Oversee corporate governance for parent company and its subsidiaries, including drafting resolutions, consents, and other corporate documents
- Assistant secretary for U.S. subsidiaries

Senior Director - Securities, Corporate Transactions and Corporate Governance

- Led legal team in the Initial Public Offering and subsequent secondary offerings
- Drafted and filed securities documents, including registration statements, annual reports, quarterly reports, current reports, and proxy statements
- Negotiated mergers and acquisitions agreements
- Led due diligence reviews of acquisition targets, including evaluation of intellectual property portfolios, significant contracts and employment issues
- Supported the Audit and Compensation Committees of the Board of Directors
- Reviewed all corporate communications, press releases, and marketing materials
- Advised human resources in connection with senior executive issues
- Executed strategic initiatives with senior executives, including supervising projects, drafting policies, and implementing procedures

Director - Global Contracting

- Negotiated complex strategic agreements with enterprise customers
- Reviewed, drafted, and negotiated a broad range of global contracts
- Provided senior management with timely legal counsel on various matters
- Assisted with strategic initiatives with various functional management
- Drafted global contracting guidelines
- Advised sales organization on contracting policies and procedures

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., Raleigh, NC
Corporate Associate
Summer 2000 & September 2001 – November 2010

Corporate Counsel

- Prepared board documents, including resolutions, consents and minutes
- Prepared corporate contracts, including supply agreements, license agreements, confidentiality agreements, and invention assignment agreements
- Negotiated and prepared international agreements during an in-house secondment
- Prepared corporate policies, including codes of conduct, insider trading, and privacy policies
- Formed and dissolved subsidiaries

Securities

- Prepared documents filed with the SEC, including registration statements, annual reports, quarterly reports, current reports, and proxy statements
- Prepared various securities legal opinions
- Represented public companies in various transactions, including going private, forward sale, and reverse triangle merger in connection with going public

Mergers and Acquisitions

- Negotiated and drafted purchase agreements and ancillary documents in stock and asset-based mergers, acquisitions, and redemption transactions

Venture Capital

- Represented venture capital and start-up companies in equity and debt financings

James Stillman Hanson
Office: 919-907-1915; Cell: [redacted]
shanson@g1therapeutics.com

University of North Carolina School of Law, Chapel Hill, NC ***Research Assistant Summer 1999***

- Assisted Professor Thomas Hazen with securities law research

Ameriprise Financial, Raleigh, NC ***Registered Representative***
(formally H&R Block Financial Advisors) ***March 1996 – May 1997***

- Managed $4.5 million; advised over 100 clients with stock selection and asset allocation

PUBLICATIONS

- *From Maine to Georgia: My Appalachian Trail Thru-Hike*

ASSOCIATIONS

- North Carolina State Bar

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-38096

G1 THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-3648180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

700 Park Offices Drive, Suite 200
Research Triangle Park, NC 27709
(Address of principal executive offices including zip code)
Registrant's telephone number, including area code: (919) 213-9835

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $.0001 par value	GTHX	**The Nasdaq Stock Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2019, was $853,358,707.

The number of shares of Registrant's Common Stock outstanding as of February 21, 2020 was 37,642,199.

Documents Incorporated by Reference

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Stockholders, scheduled to be held on June 11, 2020, are incorporated by reference into Part III of this report.

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH N/A

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Helius Medical, Inc

Physical Address: 642 Newtown Yardley Rd, Suite 100

City: Newtown State: PA Zip Code: 18940

Telephone Number: (215) 944-6105 Fax Number: N/A

Toll Free Number: N/A

E-mail: mhomnick@heliusmedical.com Website: Heliusmedical.com

Facility Manager: Joyce LaViscount

Professional qualifications and experience of facility manager:
See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☒ Practitioners ☐ Hospitals ☐ Wholesalers
☐ Other:

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other:
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address:

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Joyce LaViscount

Original Signature of Person Authorized to Submit Application, no copies or stamps

Joyce LaViscount

Print Name of Authorized Person

4/30/21

Date

Board Use Only	Date Processed: 5/19/2021 ✓	Amount: 500 Check # 13442

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Helius Medical Technologies, Inc

Corporation Name: Helius Medical, Inc

Mailing Address: 642 Newtown Yardley Road

City: Newtown State: PA Zip: 18940

Telephone: (215) 944-6105 Fax: N/A

Contact Person: Joyce LaViscount

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 07/18/2018

Registration number issued: 5277919

Stock Exchange: HSDT

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

pennsylvania
DEPARTMENT OF HEALTH

April 1, 2021

717.787.4779

Helius Medical, Inc.
642 Newtown Yardley Road, Suite 100
Newtown, PA 18940

Dear Sir or Madam:

The Pennsylvania Department of Health, Drug, Device & Cosmetic Program acknowledges that the company, Helius Medical, Inc., is an entity within the Commonwealth that is performing business activities related to the pharmaceutical, medical device, or cosmetic industry at the stated address. The company is not engaging in the physical manufacture, storage, distribution or retailing of product at this address.

The company has voluntarily provided information and has attested that no pharmaceutical product, medical device or cosmetic of any kind is physically manufactured, stored, distributed or retailed at the address stated above. This information serves only to place the company at the specified location, on file as a courtesy and does not subject it to any on-site inspection or regulatory requirements under the purview of this office. The information is recorded under record number #9500000197 and reviewed annually.

If at any time the business function changes and pharmaceutical product, medical devices or cosmetics are physically manufactured, stored, distributed or retailed at the address stated above, an application for registration/licensure will be required by Department of Health and the facility would be subject to all laws and regulations applicable to those activities. You may visit our website at https://apps.health.pa.gov/ddc/ or contact our office for additional information.

Sincerely,

Theresa A. Ritchie, R.Ph.
Drug & Device Program Specialist
Division of Home Health

Certificate of Record

Certificate No. 9500000197

Drug & Device Registration
555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

Category:
Office/Corporate Location
No product onsite

HELIUS MEDICAL, INC.
642 NEWTOWN YARDLEY ROAD, SUITE 100
NEWTOWN, PA 18940

The above business is recognized by the Department of Health as an entity that is doing business in the Commonwealth of Pennsylvania related to pharmaceuticals, medical devices, or cosmetics for which said entity **does not** physically handle, possess, transfer, manufacture, distribute, or retail pharmaceuticals, medical devices or cosmetics at the location on the certificate of record.

Issuance Date: March 25, 2019

Expiration Date: The Last Day of April, 2022

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Alison V. Beam
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

1067

Maria Herrera

From: Stacie Borngrebe <stacie.borngrebe@twolabs.com>
Sent: Tuesday, June 1, 2021 10:57 AM
To: Maria Herrera
Subject: RE: Nevada Wholesaler Application- Helius Medical, Inc
Attachments: HMI Cert Good Standing 3-2021 (002).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Maria,

I believe this is just the long form. However, it is in fact a good standing and does state that they are in good standing. It just includes the incorporation documents as well. Is there anyway they can use this one?

Thank you,

Stacie Borngrebe
Licensing Analyst
PharmaLicense

TwoLabs
PHARMA SERVICES

110 Riverbend Avenue | Suite 100 | Powell, OH | 43065
mobile 614.370.2801 | **fax** 866.259.4324
website | email | vCard | LinkedIn

Please consider the environment before printing this email.

This email and any files transmitted with it are confidential and proprietary to Two Labs, LLC and may be legally privileged and are intended solely for the use of the individual or entity to which they are addressed. If you are not the intended recipient please note that any disclosure, distribution, or copying of this email is strictly prohibited and may be unlawful. If received in error, please delete this email and any attachments and confirm this to the sender. Two Labs, LLC does not warrant or represent the information contained herein. Recipient is solely responsible for independent verification through their own representation, legal, and regulatory departments. Thank you.

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Thursday, May 27, 2021 7:25 PM
To: Stacie Borngrebe <stacie.borngrebe@twolabs.com>
Subject: RE: Nevada Wholesaler Application- Helius Medical, Inc

Hi Stacie,

In further review of the application, we noticed the Certificate of Good Standing in the application is the incorporation certificate. Can you provide the regular Certificate of Good Standing? Usually it does not include the incorporation documents submitted, I attached an example.

Thank you,

Maria H.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "HELIUS MEDICAL, INC" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF INCORPORATION, FILED THE TWENTY-SECOND DAY OF JANUARY, A.D. 2013, AT 5:55 O`CLOCK P.M.

CERTIFICATE OF AMENDMENT, FILED THE THIRD DAY OF MARCH, A.D. 2014, AT 11:31 O`CLOCK A.M.

CERTIFICATE OF MERGER, FILED THE THIRTEENTH DAY OF JUNE, A.D. 2014, AT 5:36 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTEENTH DAY OF JUNE, A.D. 2014 AT 12:01 O'CLOCK A.M.

CERTIFICATE OF AMENDMENT, CHANGING ITS NAME FROM "NEUROHABILITATION CORPORATION" TO "HELIUS MEDICAL, INC", FILED THE TWENTY-FIRST DAY OF DECEMBER, A.D. 2018, AT 10:39 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

5277919 8310

SR# 20210922496

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202748680

Date: 03-16-21

Delaware

The First State

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "HELIUS MEDICAL, INC".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HELIUS MEDICAL, INC" WAS INCORPORATED ON THE TWENTY-SECOND DAY OF JANUARY, A.D. 2013.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5277919 8310

SR# 20210922496

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202748680

Date: 03-16-21

Helius
MEDICAL TECHNOLOGIES

OWNERSHIP

Helius Medical, Inc ("Helius") is self-distributor of pharmaceutical devices. Helius Medical, Inc is a 100% wholly owned subsidiary of Helius Medical Technologies, Inc. Helius Medical Technologies, Inc. is a publicly traded company. Stock Symbol: HSDT

COMPANY INFORMATION

642 Newtown Yardley Rd., Suite 100
Newtown, PA 18940
Phone: (215)944-6047
Tax ID: 46-2057609

CORPORATE OFFICERS

Dane C. Andreeff, Interim President & CEO
Business Address:
642 Newtown Yardley Rd, Suite 100
Newtown, PA 18940

Joyce E. LaViscount, Chief Financial Officer and Chief Operations Officer
Business Address:
642 Newtown Yardley Rd, Suite 100
Newtown, PA 18940

Helius
MEDICAL TECHNOLOGIES

DESCRIPTION OF OPERATIONS

Helius Medical, Inc ("Helius") is a pharmaceutical device company. Helius Medical, Inc is a 100% wholly owned subsidiary Helius Medical Technologies, Inc. Helius develops, acquires and licenses unique and noninvasive technologies that show exceptional promise to amplify the brain's ability to heal itself. The leading candidate is the PoNS device. The PoNS device delivers translingual neurostimulation (TLNS) to potentially alter the capacity, organization and function of brain structure. Helius utilizes Keytronics EMS to product their product and utilizes FedEx for distribution of the product.

Helius' hours of operations are 8:00 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday.

CONTRACT MANUFACTURER

Helius uses the following contract manufacturer to produce product:

Keytronic EMS
7015 55th St. N
Oakdale, MN 55128

PRODUCTS

Helius products are not controlled substances. Accordingly, Helius is not required to maintain DEA registration.

The PoNS Device
FDA Owner Operator Number 10059664

Registered Agent

C T Corporation System
780 Commercial Street SE
Suite 100
Salem, Oregon 97301

Pennsylvania Department of Health

Drug, Device and Cosmetic Program
Public Lookup

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

- **Helius Medical, Inc.** 642 Newtown Yardley Road, Suite 100; Newtown, PA 18940
  Certificate(s): **9500000197** issued: 3/25/2019 10:21:00 AM expires: 4/30/2022

Back to DD&C Home

Copyright © 2009-2018 Commonwealth of Pennsylvania. All Rights Reserved.

Assembly Version 4.0.18274.4
Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
HELIUS MEDICAL, INC
642 Newtown Yardley Rd.
Suite 100
Newtown , PA 18940
Registration Number: 3015259856
FEI Number*: 3015259856
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
Helius Medical, Inc
642 Newtown Yardley Rd.
Suite 100
Newtown, PA US 18940
Owner/Operator Number: 10059664

Official Correspondent:
Lawrence Picciano
642 Newtown Yardley Rd.
Suite 100
Newtown, PA 18940
Phone: 732-6487332

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified
MJH
5/19/21

Page Last Updated: 05/17/2021
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

Establishment Registration & Device Listing

1 result found for **Establishment Registration or**
Business Trade Name : *helius*

New Search[6]

Establishment Name	▲[7] ▼[8]	Registration Number	Current Registration Yr
HELIUS MEDICAL, INC[9]	PA/USA	3015259856	2021

- Neuromuscular Tongue Stimulator To Treat Motor Deficits - Portable Neuromodulation Stimulator (PoNS)[10]

Manufacturer; Specification Developer; Complaint File Establishment

Can't find what you're looking for? Try a new search[11]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. ../cfrl/rl.cfm
7. ../cfrl/rl.cfm?start_search=1&establishmentName=helius®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorNa
8. ../cfrl/rl.cfm?start_search=1&establishmentName=helius®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorNa
9. ./rl.cfm?rid=226995
10. ./rl.cfm?lid=738810&lpcd=QCF
11. ./rl.cfm

Page Last Updated: 04/26/2021

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. ../cfrl/rl.cfm
7. ../cfrl/rl.cfm?start_search=1&establishmentName=helius®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorNa
8. ../cfrl/rl.cfm?start_search=1&establishmentName=helius®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=&OwnerOperatorNa
9. ./rl.cfm?rid=226995
10. ./rl.cfm?lid=738810&lpcd=QCF
11. ./rl.cfm

JOYCE N. LAVISCOUNT

Newtown, PA 18940 • [redacted]

C-LEVEL EXECUTIVE – FINANCE & OPERATIONS

STRATEGIC LEADERSHIP | GROWTH POSITIONING | PERFORMANCE MAXIMIZATION

Capital Market Management – Financing | Finance and Accounting | Financial Planning & Analysis | Regulatory Compliance | Organic & Acquisitional Growth | M&A - Transactional Leadership Business Operations & Integration | Cost & Cash Management | Performance Turnaround | Profitability Improvement

Results driven leader: *Capitalizing on diversity of experience to identify and resolve unforeseen challenges... ...strategizing growth and positioning businesses for long-term success.*

High-energy, roll-up-your-sleeves executive with stellar record in developing the vision and driving game-changing results, diving into unchartered waters – often in times of critical need – to achieve corporate objectives. Incisive, numbers-driven leader who adeptly leverages data to educate/inform stakeholders, assess alternatives, and gain buy-in for best-fit solutions. Solution-oriented leader whose background is enriched by diversity of experience within Fortune 100 companies, Big 4 accounting firms, and private equity-backed ventures.

Core Expertise:

- **Shaping/reshaping businesses**, providing vision and leadership in setting strategic directions and developing/implementing roadmaps to move organizations forward.
- **Strengthening organizational performance,** providing hands-on leadership and transparent communications to build/maintain staff accountability and cultivate an environment of excellence.
- **Developing and improving a company's business operations,** asking the unasked questions and challenging the status quo to spur solutioning and drive needed change.
- **Bringing public company standards to financial operations and reporting,** implementing rigorous cash management practices while establishing infrastructures to enhance financial stability and transparency.
- **Providing transactional leadership for acquisition/divestiture processes,** identifying creative, win-win solutions while providing meticulous financials and due diligence to maximize return and minimize risk.

CAREER HIGHLIGHTS

HELIUS MEDICAL TECHNOLOGIES, INC (NASDAQ - HSDT; TSX - HMT) 2015 to Present

Chief Financial Officer/Chief Operating Officer *($1.5 million/20-35 staff)*

Partnering with the CEO, playing a key leadership role in all strategic, operational and financial aspects for innovative neuro technology-based medical device company. Participated in raising over $90M in public equity financings and private placements for this startup company to fund all stages of development. Secured up-listings to both Nasdaq and Toronto stock exchanges. Exceptional leadership and problem-solving skills to navigate through complex circumstances of an FDA denial letter leading to an 80% decline in market capitalization; resulting 30% layoffs while at the same time stabilizing the operations to launch our novel technology in Canada.

- Strategic Planning and Execution – successfully prioritize regulatory, clinical, manufacturing, commercial options in a complex and challenging regulatory and financial environment to drive achievement of key milestones.
- Broad functional management responsibility and experience including product development, manufacturing, clinical and commercial operations, investor relations, IT, human resources in addition to finance/accounting
- Preparation and presentation of marketing materials, financial projections and due diligence materials for potential investors, third-party business partners and SEC filings.
- Regulatory Compliance – SEC, Internal Controls Environment, Management Representative for Quality Management System responsible for obtaining ISO 13485 and MDSAP Certifications.
- Data capture through product software and external system to gather compliance and usage data to support collection of real-world evidence to drive product clearance, adoption and reimbursement.
- Design, develop and implement all people, processes and systems infrastructure (Microsoft Dynamics, BI and Data Warehouse) required to transition from start-up development stage through commercialization.

MEDIMEDIA USA, INC 2012 to 2015

Chief Operating Officer *(MediMedia Health, $18.5 million/65+ staff, 2015)*
Chief Financial Officer *(MediMedia Pharma Division, 3 businesses - $72 million/15 staff, 2012 to 2015)*

Held key leadership roles during period of rapid change and reorganization, leading financial and operational initiatives to stabilize results, create value for investors, and maintain long-term health of core business. Completed 3 complex sale transactions in <2 years while managing day-to-day health of remaining business.

- Joining company experiencing a business downturn, stepped in to shore up financial footings. Developed and implemented strategies to address identified deficiencies – declining revenue, EBIDTA losses, cash flow issues, restrictive cost structures, and lack of transparency into the business results.
- Built top-notched accounting/finance team renowned for providing credible, high-quality financial data that improved business decision-making and financial transactions. Created automated customer, product line, and program profitability reports that surpassed public company reporting standards and facilitated financial management.
- As COO of MediMedia Health (a Pharma Division unit), orchestrated performance turnaround, recognizing opportunity and driving initiatives – systems consolidation, strategic partnerships, value-driven pricing structure and improved contracting terms – that reduced costs and improved cash flow.
- Illuminated downturn in/drawbacks of significant piece of business (40% of division revenue), driving decision to carve out and sell money loser in strategic move that improved financial positioning and added $3.7 million to bottom line. Leaving no stone unturned in eking out value, awarded employee bonuses for first time in 5 years.
- Disentangled fully integrated business, then capitalized on opportunity to recreate systems, saving $5 million. Representative of forward-thinking contributions, envisioned lease of CRM software, capturing $65,000 in monthly savings while avoiding development costs ($500,000 to start up and one year of development time).
- Executed 3 complex sales – 2 concurrently –delivering **9x purchase price** in 4-bid auction process in one and **10x purchase price** in another. Worked directly with senior-level stakeholders to complete transactions.

APTALIS PHARMA INC. / EURAND PHARMACEUTICALS, INC. 2010 to 2012

Executive Director, Group Controller, North America *(Aptalis $600 million/20 staff, 2011 to 2012)*
Vice President Finance, US *(Eurand/12 staff, 2010)*

Reporting to corporate CFO following Eurand's acquisition, led finance unit supporting $440+ million North American operation, businesses representing 75% of total company revenue. Previously served on US senior management team and as officer for 2 Eurand operating units. Evaluated M&A opportunities and drove integration.

- Played critical role in integration activities, leading 20-member finance team – across 4 locations – in aligning resources, finance systems, processes, and accounting policies. Led cross-functional team that executed legal entity consolidation strategy and ensured cross-company compliance with federal Sunshine Act.
- Co-led Synergy Capture Team that delivered on $54 million in saving opportunities, identifying solutions to facilitate successful integration and capture synergistic savings.
- Standardized accounting processes as VP Finance for Eurand. Served on leadership committees for pricing, compliance, and 401(k) benefits. Guided US ERP implementation as member of Steering Committee.
- Developed financial models and other tools to improve ability to quickly and effectively evaluate business development opportunities.

ENDO PHARMACEUTICALS INC. 2004 to 2009

Vice President, Sales Operations & Training *(2008 to 2009, 16 staff)*
Chief Accounting Officer (CAO)/Vice President, Finance Operations *(2006 to 2008, 28 staff)*
Vice President, Investor Relations and Corporate Communications *(2008)*
Vice President, Strategic Plan Program Management Office *(2007 to 2008)*
Interim Chief Financial Officer *(2006)*
Vice President, Financial Planning, Reporting and Analysis *(2004 to 2006)*

As senior management's go-to resource, developed breadth of experience across functions during period of explosive growth ($600 million to $1.5 billion in revenue). Transformed/strengthened financial operations. Developed and implemented strategies for sales operations and corporate/investor communications. Provided guidance to drive high-level executive and business decision making.

- Named CAO when incumbent CFO retired, also took on interim CFO duties, building reputation as "just get it done" leader. Oversaw $20.5 million acquisition and integration, settled patent infringement case, and restructured co-development agreement during tenure.
- Transformed financial operations, putting focus on roles/responsibilities, systems/processes, and policies/procedures to strengthen finance team's ability to deliver value-added contributions and drive significant business results.
- Tapped to develop corporate growth strategy to set new direction focused on diversification to target acquisition opportunities, created high-level strategic plan, introducing cross-functional resource allocation to prioritize investments.
- Taking on investor relations/corporate communications role, developed and implemented differentiated communication strategy built around adapting messaging to audience wants and needs.
- In Sales Ops leadership role, propelled performance improvement with creative solutions, including a weighted variable incentive plan based on territory potential that increased productivity and ROI of 900+ field reps.
- Led design and launch of *Performance Frameworks*, a competency-based training and development curriculum to enhance sales effectiveness. Introduced targeting tool – more advanced than big pharma tools – that allowed sales team to select and prioritize physicians to call on to maximize return.

Early Career: Held director-level financial roles with Pfizer, guiding 2 separate business units (4 years). Served as senior manager (financial analysis) for Bristol-Myers Squibb (10+ years). Supervised audits in early-career role with Ernst & Young (4+ years).

Bachelor of Arts, Business Administration (concentration in Accounting), Franklin and Marshall College, 1984
Certified Public Accountant, State of New Jersey (Voluntary Inactive Status)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the Fiscal Year Ended December 31, 2017

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the transition period from _____ to _____
Commission File No. 000-55364



HELIUS MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

WYOMING	**36-4787690**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

Suite 100, 642 Newtown Yardley Road
Newtown, Pennsylvania, 18940
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 944-6100

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
None	**None**

Securities registered pursuant to Section 12(g) of the Act: Class A Common Stock

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section §232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

Emerging growth company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

The aggregate market value of the common equity held by non-affiliates of the registrant on June 30, 2017, based on the closing price on that date of USD$7.80, was approximately $99,372,392. As of March 5, 2018, there were 20,241,135 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2018 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2017.

TABLE OF CONTENTS

Item	Description	Page
	PART I	4
ITEM 1.	BUSINESS	4
ITEM 1A.	RISK FACTORS	23
ITEM 1B.	UNRESOLVED STAFF COMMENTS	38
ITEM 2.	PROPERTIES	38
ITEM 3.	LEGAL PROCEEDINGS	39
ITEM 4.	MINE SAFETY DISCLOSURES	39
	PART II	40
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	40
ITEM 6.	SELECTED FINANCIAL DATA	40
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	41
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	47
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	47
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	47
ITEM 9A.	CONTROLS AND PROCEDURES	48
ITEM 9B.	OTHER INFORMATION	48
	PART III	49
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	49
ITEM 11.	EXECUTIVE COMPENSATION	49
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	49
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	49
ITEM 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES	49
	PART IV	50
ITEM 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES	50
ITEM 16.	FORM 10-K SUMMARY	52
SIGNATURES		

In this Annual Report on Form 10-K, unless otherwise specified, references to "we," "us," "our," "Helius" or "the Company" mean Helius Medical Technologies, Inc. and its wholly-owned subsidiaries, NeuroHabilitation Corporation, or NHC, and Helius Medical Technologies (Canada), Inc., unless the context otherwise requires. All financial information is stated in U.S. dollars unless otherwise specified. Our financial statements are prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or the Annual Report, includes certain statements that may constitute "forward-looking statements." All statements contained in this Annual Report, other than statements of historical facts, that address events or developments that the Company expects to occur, are forward-looking statements. These statements are based on management's expectations at the time the statements are made and are subject to risks, uncertainty, and changes in circumstances, which may cause actual results, performance, financial condition or achievements to differ materially from anticipated results, performance, financial condition or achievements. All statements contained herein that are not clearly historical in nature are forward-looking and the words "anticipate," "believe," "calls for," "could" "depends," "estimate," "expect," "extrapolate," "foresee," "goal," "intend," "likely," "might," "plan," "project," "propose," "potential," "target," "think," and similar expressions, or that events or conditions "may," "should occur" "will," "would," or any similar expressions are generally intended to identify forward-looking statements.

The forward-looking statements in this Annual Report include but are not limited to statements relating to: clinical development plans, product development activities, other products not yet developed or acquired, our product candidate success, plans for U.S. Food and Drug Administration, or FDA, filings and their subsequent approvals, other foreign or domestic regulatory filings by us or our collaboration partners, including filings with Health Canada, CE Mark and the Therapeutic Goods Administration, our ability to commercialize the product(s), either independently or with collaboration partners, the safety and efficacy of our product candidate, the timeline for our improvement plans, our market awareness, our ability to compete effectively, the ability and limitation of our manufacturing source(s), our distribution network, the adequacy of our intellectual property protection, our future patent approvals, potential infringement of our intellectual property, future litigation waged against us and its outcome, any product liability we may incur, the sufficiency of our operating insurance, including sufficient product liability insurance, our limited operating history, our dependence on a small number of employees, employee conflicts of interest, our dependence on outside scientists and third party research institutions, our future expenses and cash flow, our ability to become profitable, our future financing arrangements, our ability to accurately report our financial position, our accountants' future perspective including any going concerns, our ability to maintain effective internal controls, any future stock price, the potential dilution of the stock, future sales of the Company's equity securities, any future Financial Industry Regulatory Authority sales practice requirements, future disclosure requirements, future regulatory risks, our relationship with the U.S. Army, our ability to build the necessary commercial infrastructure and to use existing reimbursement codes or receive reimbursement codes from the American Medical Association and the U.S. Department of Health and Human Services, and our ability to receive reimbursement coverage under Medicare, Medicaid or under other insurance plans. These and additional risks and uncertainties are more fully described in this Annual Report and our other public filings with the Securities and Exchange Commission or SEC.

Although we believe the expectations expressed in such forward-looking statements are based on reasonable assumptions at the time they were made, they are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Forward-looking statements are not guarantees of future performance and actual results may differ significantly from such forward-looking statements. Factors that could cause the actual results to differ materially from those in the forward-looking statements include future economic, competitive, reimbursement and regulatory conditions; new product introductions, demographic trends, the intellectual property landscape, litigation, financial market conditions, continued availability of capital, and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Undue reliance should not be placed on forward looking statements which speak only as of the date they are made. Except as required by applicable securities laws, we undertake no obligation to update or alter these forward-looking statements (and expressly disclaims any such intention or obligation to do so) in the event that management's beliefs, estimates, opinions, or other factors should change.

INDUSTRY AND MARKET DATA

In this Annual Report, we reference information, statistics and estimates regarding the medical devices and healthcare industries. We have obtained this information from various independent third-party sources, including independent industry publications, reports by market research firms and other independent sources. This information involves a number of assumptions and limitations, and we have not independently verified the accuracy or completeness of this information. Some data and other information are also based on the good faith estimates of management, which are derived from our review of internal surveys, general information discussed in the industry, and independent sources. We believe that these external sources and estimates are reliable but have not independently verified them. The industries in which we operate are subject to a high degree of uncertainty, change, and risk due to a variety of factors, including those described in "Item 1A. Risk Factors." These and other factors could cause results to differ materially from those expressed in this report and other publications.

PART I

ITEM 1. BUSINESS

Overview

We are a medical technology company focused on the development of products for the treatment of neurological symptoms caused by disease or trauma. We seek to develop, license or acquire unique and noninvasive platform technologies that amplify the brain's ability to heal itself.

Many patients with brain injury or brain-related disease have disrupted neural networks that result in their brains being unable to correctly or efficiently carry neural impulses, which are responsible for directing bodily functions like movement control or sensory perception. Our first product in development, known as the portable neuromodulation stimulator or PoNS®, device, is designed to enhance the brain's ability to compensate for this damage. The PoNS Treatment is a combination of our PoNS device and functional, targeted physical or cognitive therapy, and is currently being developed for the treatment of movement, gait and balance disorders in patients with traumatic brain injury, or TBI, and other chronic neurological diseases.

We recently completed our registrational clinical trial of the PoNS Treatment for mild- to moderate TBI, in which we observed statistically and clinically significant increases in composite sensory observation test scores. Based on the safety and efficacy results from this clinical trial, we intend to submit a request for FDA marketing authorization for the treatment of chronic balance deficit due to mild- to moderate-TBI via the FDA's de novo classification process in the first half of 2018. In addition, we intend to submit applications for marketing authorizations in Canada, the European Union and Australia during the first half of 2018.

The PoNS Treatment

The PoNS Treatment consists of an investigational medical device that is comprised of two major components, an electric pulse generator and a replaceable mouthpiece combined with physical or cognitive therapy. The PoNS device delivers specially-patterned electrical stimulation developed to mirror nerve impulses to the brain through 143 gold-plated electrodes on the mouthpiece which is placed on the tongue. For 20 minutes the electrical stimulation, called translingual neurostimulation, is coupled with physical or cognitive therapy, which consists of condition specific physical, relaxation and cognitive exercises, based on the patient's functional deficits. Clinical research has shown that electrical stimulation of the tongue activates two major cranial nerves – the lingual nerve, a part of the trigeminal nerve, and the chorda tympani, a part of the facial nerve. Electrical stimulation of the cranial nerves creates a flow of neural impulses that are then delivered directly into the brain stem and cerebellum – the main control centers for multiple life functions including sensory perception and movement. From the brain stem, these impulses travel throughout the brain and activate or reactivate neurons and structures involved in human function such as the cortex, spinal cord and potentially the entire central nervous system. Researchers believe that sustained stimulation initiates a sequential cascade of changes in the actual interconnected nuclei, or neuronal network, the fundamental connections between the anatomical components of the brain. The PoNS device is also a smart device with built in technology to allow tracking of the patient use, including time and intensity of treatments.

Design

The PoNS device is ergonomically designed for patient comfort, is relatively light, contains a replaceable hygienic mouthpiece, and a rechargeable battery with built-in technology that allows for technical data logging and communications. See Figure 1.



Figure 1
The portable neuromodulation stimulator, PoNS device

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☑ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Novavax, Inc.

Physical Address: 21 Firstfield Road

City: Gaithersburg State: MD Zip Code: 20878

Telephone Number: (240) 268-2000 Fax Number: (240) 268-2100

Toll Free Number: N/A

E-mail: Wmeitin@novavax.com Website: novavax.com

Facility Manager: Wayne Meitin

Professional qualifications and experience of facility manager: See Attachment B

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers
☑ Other: Distributors

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other:
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☑
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)
See Attachment C

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment C
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Wayne Meitin

Original Signature of Person Authorized to Submit Application, no copies or stamps

Wayne Meitin — Print Name of Authorized Person

2/22/2021 — Date

Board Use Only	Date Processed:	Amount: 500 (cc)

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: N/A

Corporation Name: Novavax, Inc.

Mailing Address: 21 Firstfield Road

City: Gaithersburg State: MD Zip: 20878

Telephone: (240) 268-2000 Fax: (240) 268-2100

Contact Person: Wayne Meitin

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K. See Attachment D

Date of Incorporation: June 1987

Registration number issued: 2129598

Stock Exchange: NASDAQ

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment E

List of officers and directors. See Attachment F

DISTRIBUTOR REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

122610 122610

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Novavax Inc
21 Firstfield Road
Gaithersburg MD 20878

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Novavax Inc
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2023)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D06934	05/31/2023

SIGNATURE OF BEARER

122610

State of Maryland 122610

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Novavax Inc
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2023)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D06934	05/31/2023

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Distributor Change of Information

A Distributor must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

MARYLAND
Department of Health
Larry J. Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Robert R Neall, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Kevin M. Morgan, Board President, Deena Speights-Napata, Executive Director

PHARMACY OPENING INSPECTION FORM

Maryland Pharmacy Permit Number	:	
Inspection Date	:	05/17/2021
Corporate Pharmacy Name	:	Novavax Inc
Pharmacy Name-Doing Business as (d/b/a) or Trade Name	:	
Street Address	:	21 Firstfield Road, Gaithersburg, MD, 20878
Business Telephone Number	:	240-268-2000
Business Fax Number	:	240-268-2100
Arrival Time	:	12:20
Departure Time	:	12:28
Name of Inspector	:	Shanelle Young

1. PHYSICAL REQUIREMENTS AND EQUIPMENT

◉ Yes ○ No ○ N/A	The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
◉ Yes ○ No ○ N/A	The pharmacy has a refrigerator(s), solely for the storage of drugs requiring refrigeration, with a thermometer or a temperature monitoring device. COMAR 10.34.07.01B
◉ Yes ○ No ○ N/A	The pharmacy has additional equipment to enable it to prepare and dispense prescriptions properly consistent with its scope of practice. COMAR 10.34.07.02
◉ Yes ○ No ○ N/A	The pharmacy has hot and cold running water.
◉ Yes ○ No ○ N/A	The pharmacy has a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03
◉ Yes ○ No ○ N/A	The pharmacy has online resources. HO §12-403(b)(15)
◉ Yes ○ No ○ N/A	The pharmacy possesses the current edition of The Maryland Pharmacy Laws and Regulations. HO §12-403(b)(10)(ii)

2. SECURITY COMAR 10.34.05

◉ Yes ○ No	The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

This pharmacy has security staff, an alarm system and video monitoring to prevent unauthorized entry.

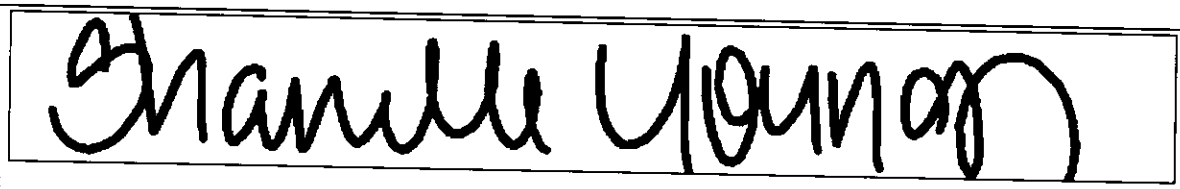
◉ Yes ○ No	The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Opening Inspection:
- ◉ Pass
- ○ Fail
- ○ Pending for Review

INSPECTOR'S COMMENTS:

This inspection was virtually conducted with representative, Suzanne Sollecito. The requirements as listed above were observed through documented communication with the facility staff to ensure that this facility meets the minimum requirements by state law. Documents attached to this inspection were provided during virtual communication with representative, Suzanne Sollectio.

This opening inspection is for a virtual manufacturer. The alarm system test was witnessed on May 13, 2021, attached is the activity report printed from the security department per Suzanne Sollectio.

Inspector Signature:		
Pharmacist Name (Print):	Suzanne Sollecito	Date: 05/17/2021
Received a copy of this inspection report:		

Supporting Documents.

410-764-4755 - Fax 410-384-4137 - Toll Free 800-542-4964
MDH 1-877-463-3464 - Maryland Relay Service 1-800-735-2258
Web site: https://health.maryland.gov/pharmacy/Pages/index.aspx

Attachment E

Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NOVAVAX, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2129598 8300

SR# 20210586128

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202574116

Date: 02-23-21

Maria Herrera

From: Pharmacy Board
Sent: Wednesday, May 5, 2021 10:02 AM
To: Maria Herrera
Subject: Fw: Novavax, Inc. - Nevada Officer Change Application

---

From: Kunkel, Lisa M. <kunkel@porziols.com>
Sent: Wednesday, May 5, 2021 7:50 AM
To: Pharmacy Board
Subject: Novavax, Inc. - Nevada Officer Change Application

Dear Sir or Madam,

Effective immediately, Novavax, Inc. (Novavax) had a change in corporate officers. Provided below is the updated corporate officer list.

Stanley Erck
President and CEO

John Herrmann III
Executive Vice President and Chief Legal Officer

John J. Trizzino*
Executive VP, Chief Commercial Officer, Chief Business Officer, Interim Chief Financial Officer

*new corporate officer

Please note that Novavax's virtual manufacturer application is currently pending with your office. Kindly update the file accordingly.

Please advise if any additional documentation is required.

Kind regards,

Lisa

Lisa M. Kunkel
Associate Manager, Licensing Services
PORZIO LIFE SCIENCES, LLC
A wholly-owned subsidiary of PORZIO, BROMBERG & NEWMAN, P.C.
100 Southgate Parkway, P.O. Box 1997 | Morristown, NJ 07962-1997

P: 973.889.4221 | F: 973.538.5146
kunkel@porziols.com | porziolifesciences.com

Attachment F

Corporate Officer and Director Information

Novavax, Inc.

Corporate Officers:

Stanley Erck
President and CEO

Greg Covino
Chief Financial Officer

John Herrmann III
Executive Vice President and Chief Legal Officer

Board of Directors:

Stanley Erck
Richard Douglas
Gregg Alton
Gary Evans
Rachel King
Margaret McGlynn
Michael McManus Jr.
Rajiv Modi
David Mott

Attachment B

Facility Manager's Resume

Wayne L. Meitin

Alpharetta, GA 30009 • [redacted] • LinkedIn: https://www.linkedin.com/in/waynemeitin

MANAGED MARKETS / TRADE & DISTRIBUTION LEADER

Multifaceted **BioPharmaceutical Trade / Specialty Pharmacy & Distribution Executive** with extensive experience among diverse Managed Markets / Trade & Distrubution channels. A successful track record with world-class pharmaceutical manufacturers including progressive career advancement and numerous performance awards. Successful management of teams and high impact corporate accounts. Multi therapeutic area experience including specialty biologics / retail / buy & bill products with varying reimbursement and distribution mechanisms.

PROFESSIONAL EXPERIENCE

AMAG Pharmaceuticals **Waltham, MA** (remote) **03/2017 – present**

Pharmaceutical company focused on delivering medicines across a range of therapeutic areas including hematologic disorders, womens health, and maternal health

Executive Director, Trade & Distribution 09/2019 – present
Senior Director, Trade & Distribution 03/2017 – 09/2019

Hired into the Senior Director role to create a comprehensive strategic distribution strategy that meets the needs of current and future portfolio products. This strategy and execution encompasses specialty pharmacy, specialty distribution, wholesale distribution, retail pharmacy, and 3PL channels. Lead the National Account Team that manages over 70 accounts across all distribution channels

- Successful incentive program for Intrarosa®, AMAG's first retail pharmacy product, resulted in 12,000 units available for pull through on national wholesale pharmacy shelves prior to the launch.
- Built and executed the Intrarosa® retail pharmacy launch, which resulted in exceeding our goal by 2700 units
- Led the trade team in our re-negotiation of our national wholesale distribution agreements, resulting in overall net savings of $6.5 million dollars, with no loss in service levels realized.
- Have consistently met and/or exceeded ex factory goals for Feraheme® for the past 11 quarters
- Built, and executed an exclusive specialty pharmacy network to support the successful launch of Vyleesi®.
- 2019 AMAG Presidents Club winner

AstraZeneca **Wilmington, DE** (remote) **09/2014 – 03/2017**

Multi-national biopharmaceutical company, focusing on the commercialization of oncology, cardiovascular, metabolic, respiratory, and autoimmune therapies

Senior Director, National Channel Team 09/2014 – 03/2017

Promoted in order to successfully facilitate the launch of three major AstraZeneca brands within the assigned account segments

- Led integrated account team focused on two large core customers – Cardinal Health (Wholesale) and CVS Health, and other downstream customers. Team responsibilities spanned wholesale, retail and specialty divisions servicing entire AZ portfolio
- Team was first to make Tagrisso® available in the specialty distribution channel, as a result of our successful negotiation with Cardinal Specialty. This enabled AZ to realize rapid maket uptake of these brands on schedule.
- Successfully led team on the negotiation and successful addition of CVS Specialty, the worlds largest specialty pharmacy, into the limited specialty pharmacy network servicing patients for the oncology launch brands Tagrisso® and Iressa®.
- Successfully led team in our agreement renegotiation with Cardinal Health. Payment terms were favorably negotiated below our approved targeted rates.
- Built working relationships with C-Suite / VP levels decision makers with CVS Health and Cardinal Health, in addition to other prominent distributors and retailers.
- Extensive internal interface among AstraZeneca brand leaders, corporate leaders for well developed, Trade Channel customer projects

MedImmune (AZ biologics division) Gaithersburg, MD **05/2000 – 09/2014**

National Account Director, Trade & Distribution 08/2007 – 09/2014
Promoted into role to design and build out the distribution network for the newly approved refrigerated formulation of FluMist®, an influenza vaccine

- Managed Wholesale, Retail, and Specialty Pharmacy Distribution (SPP) channels for FluMist®, and Synagis®
- Grew FluMist® dose volume in excess of 600% over a 7- year period from 2007 (1.1M doses) to 2014 (6.1M doses)
- Negotiated favorable distribution agreements on an annual basis, delivering positive ROI while limiting GtN impact
- Spearheaded the FluMist® Plus and FluMist® Replacement marketing programs
- 2010 President's Club, 2010 Circle of Excellence winner

Product Manager, Oncology Marketing 01/2006 – 08/2007

- Successfully managed a $1.7M promotional budget for all MedImmune's oncology products
- Led a cross functional team that developed the "stranded" brand theme and ad campaign for Ethyol®. This campaign supported a trajectory turn around for the brand,which landed a 4% increase in volume for a brand YOY.
- Led our oncology portfolio relationship with outside advertising agencies
- Led convention and symposia strategies and tactics
- Led Sales Force Advisory Committee initatives

National Account Manager, Oncology 10/2004 – 01/2006

- Successfully renegotiated favorable-term contracts with key GPOs, ION, US Oncology
- Collaborated with Medicare carriers BCBS AL & AR to optimize reimbursement levels
- **Accomplishments:** Improved GtN metrics YOY

Senior Oncology Specialist 05/2000 – 10/2004

- Established and developed relationships with medical and radiation oncologists throughout GA, championing the use of Ethyol® through "Buy & Bill" procurement.
- Consistently exceeded annual sales objectives during tenure:
  - Ranked between #2 and #5 nationally each year.
  - Regional field sales trainer for 2001, 2002, and 2003.
- 2003, 2004 President's Club winner

Roche Laboratories **Atlanta, GA** **06/1996 – 05/2000**

Oncology Sales Representative

- Established and developed relationships with medical oncologists throughout the southeast, championing the use of Xeloda®, a treatment for colorectal, breast, and colon cancer, and Roferon-A, a treatment for hepatitis.
- Facilitated regional launch of Xeloda® in 3 key southern states.
- 1997, 1998 Special Achievement Award winner

Schering-Plough Corporation **Miami / Ft. Lauderdale, FL** **05/1992 – 06/1996**

Oncology Sales Representative - Fort Lauderdale, FL 03/1994 – 06/1996
Professional Sales Representative - Miami, FL 05/1992 – 03/1994

EDUCATION

BS, Finance, Florida State University

PROFESSIONAL DEVELOPMENT

Management Assessment Program, Psychological Consultants, Inc. – April 2014
Strategic Thinking & Planning, The Brooks Group – June 2014
Negotiation and Leadership, Harvard Law School – May 2013
Management Development Training, MedImmune – completed January 2004

Attachment C

Nature of Business and FDA Registration

Novavax, Inc. (Novavax) is a virtual manufacturer of a prescription drug. Novavax will utilize contract manufacturers to produce its product and a licensed third party logistics provider to warehouse and distribute its product. Novavax will not physically manufacture or distribute any product. Provided below is the contact information for the contract manufacturers and third party logistics provider. In addition, Enclosed is a copy of Novavax's FDA labeler code registration.

Contract Manufacturers

Par Sterile Products LLC
870 Parkdale Rd.
Rochester, MI 48307
FDA Registration #: 1818977

Jubilant HollisterStier LLC
3525 North Regal Street
Spokane, WA 99207
FDA Registration #: 3010477

Third Party Logistics Provider

UPS Supply Chain Solutions, Inc.
6204 New Cut Rd.
Fairdale, KY 40118

UPS Supply Chain Solutions, Inc.
2260 Outer Loop Rd.
Louisville, KY 40219

Marylyn Oparaugo

To: edrls@fda.hhs.gov
Subject: RE: Labeler Code Request Approved

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, September 18, 2020 4:58 AM
To: Marylyn Oparaugo <MOparaugo@Novavax.com>
Subject: Labeler Code Request Approved

[SENDER IS EXTERNAL TO NOVAVAX]

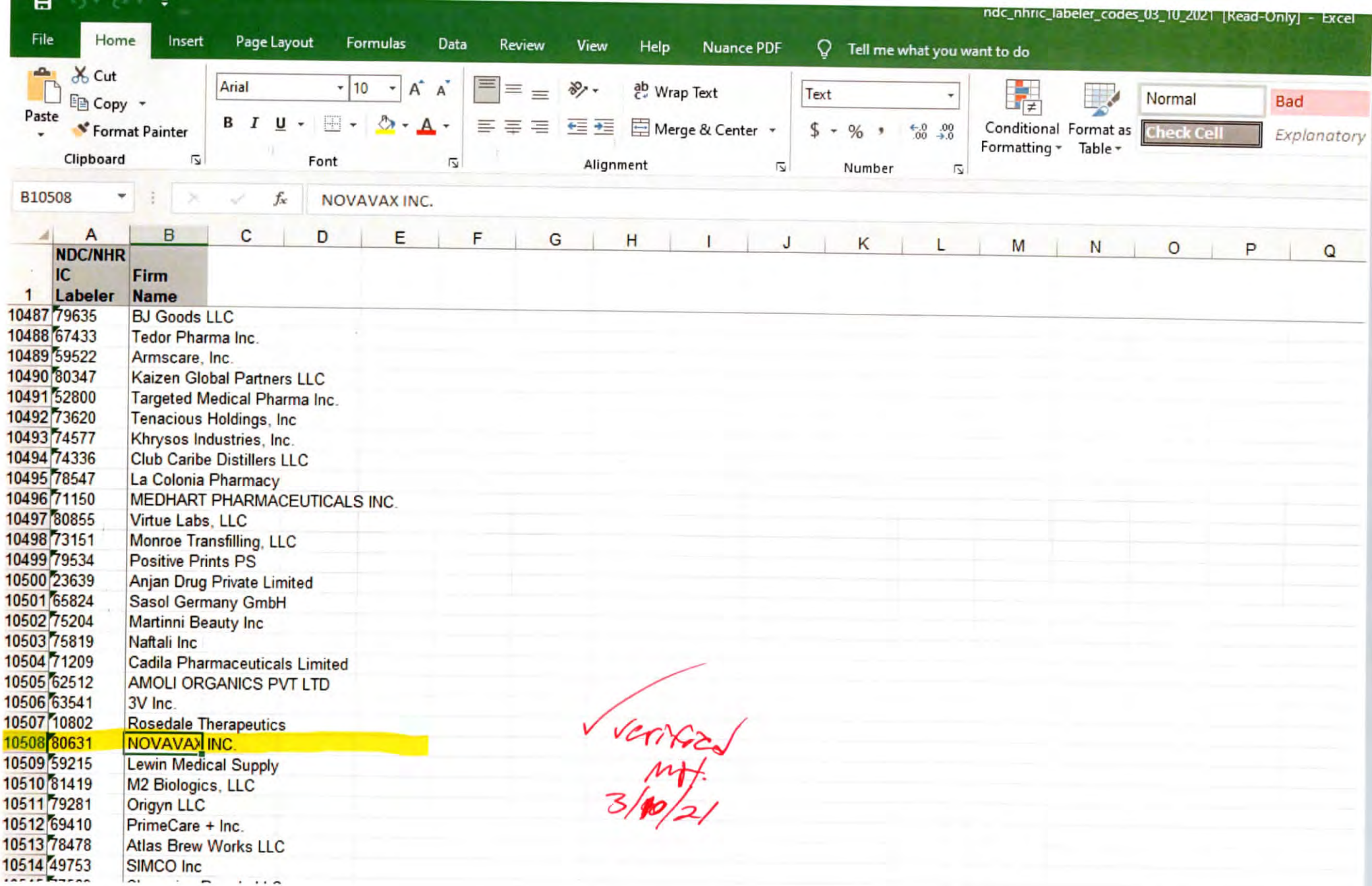
eDRLS - Electronic Drug Registration & Listing System

Current Date: 18-SEP-2020
Labeler DUNS: 808837520
Labeler Name: NOVAVAX INC.
Labeler Code Assigned: 80631

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).



ndc_nhric_labeler_codes_03_10_2021 [Read-Only] - Excel

File Home Insert Page Layout Formulas Data Review View Help Nuance PDF Tell me what you want to do

Cut Copy Format Painter Paste Clipboard

Arial 10 Font

Wrap Text Merge & Center Alignment

Text Number

Conditional Formatting Format as Table

Normal Bad Check Cell Explanatory

B10508 NOVAVAX INC.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	NDC/NHRIC Labeler	Firm Name															
10487	79635	BJ Goods LLC															
10488	67433	Tedor Pharma Inc.															
10489	59522	Armscare, Inc.															
10490	80347	Kaizen Global Partners LLC															
10491	52800	Targeted Medical Pharma Inc.															
10492	73620	Tenacious Holdings, Inc															
10493	74577	Khrysos Industries, Inc.															
10494	74336	Club Caribe Distillers LLC															
10495	78547	La Colonia Pharmacy															
10496	71150	MEDHART PHARMACEUTICALS INC.															
10497	80855	Virtue Labs, LLC															
10498	73151	Monroe Transfilling, LLC															
10499	79534	Positive Prints PS															
10500	23639	Anjan Drug Private Limited															
10501	65824	Sasol Germany GmbH															
10502	75204	Martinni Beauty Inc															
10503	75819	Naftali Inc															
10504	71209	Cadila Pharmaceuticals Limited															
10505	62512	AMOLI ORGANICS PVT LTD															
10506	63541	3V Inc.															
10507	10802	Rosedale Therapeutics															
10508	80631	NOVAVAX INC.															
10509	59215	Lewin Medical Supply															
10510	81419	M2 Biologics, LLC															
10511	79281	Origyn LLC															
10512	69410	PrimeCare + Inc.															
10513	78478	Atlas Brew Works LLC															
10514	49753	SIMCO Inc															

verified MT. 3/10/21

1101

Attachment D

SEC Form 10K

Enclosed are the first ~~15~~ 14 pages of Novavax, Inc.'s latest SEC 10-K filing. Note the full report is 93 pages. To view the full report, please visit:
https://ir.novavax.com/sec-filings/sec-filing/10-k/0001104659-20-031944

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to .

Commission File No. 000-26770

NOVAVAX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**21 Firstfield Road, Gaithersburg, Maryland 20878**	**22-2816046**
(State of incorporation)	*(Address of principal executive offices)*	*(I.R.S. Employer Identification No.)*

Registrant's telephone number, including area code: (240) 268-2000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, Par Value $0.01 per share	NVAX	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: Not Applicable

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant had elected not to use the extended transition period for complying with any new or revised financial accounting standards provide pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant (based on the last reported sale price of Registrants common stock on June 30, 2019 on the Nasdaq Global Select Market) was approximately $138,300,000.

As of March 6, 2020, there were 51,528,841 shares of the Registrant's common stock outstanding.

Documents incorporated by reference: Portions of the Registrant's Definitive Proxy Statement to be filed no later than 120 days after the fiscal year ended December 31, 2019 in connection with the Registrant's 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent indicated herein.

NOVAVAX, INC.

TABLE OF CONTENTS

		Page
	PART I	
Item 1.	BUSINESS	4
Item 1A.	RISK FACTORS	13
Item 1B.	UNRESOLVED STAFF COMMENTS	34
Item 2.	PROPERTIES	34
Item 3.	LEGAL PROCEEDINGS	34
Item 4.	MINE SAFETY DISCLOSURES	34
	PART II	
Item 5.	MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	35
Item 6.	SELECTED FINANCIAL DATA	36
Item 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	37
Item 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	47
Item 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	48
Item 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	48
Item 9A.	CONTROLS AND PROCEDURES	48
Item 9B.	OTHER INFORMATION	49
	PART III	
Item 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	49
Item 11.	EXECUTIVE COMPENSATION	49
Item 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	49
Item 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	50
Item 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	50
	PART IV	
Item 15.	EXHIBITS AND FINANCIAL STATEMENT SCHEDULES	50
Item 16.	FORM 10-K SUMMARY	55

CERTAIN DEFINITIONS

All references in this Annual Report on Form 10-K to "Novavax," the "Company," "we," "us" and "our" refer to Novavax, Inc. and its wholly-owned subsidiary, Novavax AB (unless the context otherwise indicates).

NOTE REGARDING TRADEMARKS

Novavax™, NanoFlu™, Matrix-M™, Matrix™, Prepare™, Resolve™, and ResVax™ are trademarks of Novavax. Any other trademarks referred to in this Annual Report on Form 10-K are the property of their owners. All rights reserved. We do not intend our use or display of other companies' trade names or trademarks to imply an endorsement or sponsorship of us by such companies, or any relationship with any of these companies.

FORWARD-LOOKING INFORMATION

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. Please also see the disclaimer under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

PART I

Item 1. BUSINESS

Overview

Novavax, Inc., together with our wholly-owned Swedish subsidiary, Novavax AB, is a late-stage biotechnology company that promotes improved global health through the discovery, development and commercialization of innovative vaccines to prevent serious infectious diseases. Using innovative proprietary recombinant nanoparticle vaccine technology, we produce vaccine candidates to efficiently and effectively respond to both known and emerging disease threats.

We were incorporated in 1987 under the laws of the State of Delaware. Our principal executive offices are located at 21 Firstfield Road, Gaithersburg, Maryland, 20878, and our telephone number is (240) 268-2000. Our common stock is listed on the Nasdaq Global Select Market under the symbol "NVAX."

Our vaccine candidates, including our lead candidates, NanoFlu™ and ResVax™, are genetically engineered, three-dimensional nanostructures of recombinant proteins critical to disease pathogenesis and may elicit differentiated immune responses, which may be more efficacious than naturally occurring immunity or traditional vaccines. Our technology targets a variety of infectious diseases. We are also developing proprietary immune stimulating saponin-based adjuvants at Novavax AB, our wholly owned Swedish subsidiary. Our lead adjuvant, Matrix-M™, has been shown to enhance immune responses and has been well-tolerated in multiple clinical trials.

Product Pipeline

Program	Current Development Stage
Seasonal Influenza	
·**NanoFlu (Older Adults)**[1]	Phase 3
Respiratory Syncytial Virus ("RSV")	
·**ResVax**[2] **(Infants via Maternal Immunization)**	Phase 3
·**Older Adults**[1]	Phase 2
·**Pediatrics**	Phase 1
Combination Seasonal Influenza/RSV[1]	Preclinical
Ebola Virus ("EBOV")[1]	Phase 1
Coronavirus ("COVID-19")[1]	Preclinical

(1) Includes Matrix-M adjuvant
(2) Supported by a grant of up to $89.1 million from the Bill & Melinda Gates Foundation ("BMGF")

A summary and status of these vaccine programs follows:

Seasonal Influenza

NanoFlu Program (Older Adults)

Influenza is a world-wide infectious disease with serious illness generally occurring in more susceptible populations such as children under 18 years old and older adults, but also occurring in the general population. According to influenza vaccines forecasts by Datamonitor in 2013, the market for seasonal influenza vaccines is expected to grow from approximately $3.2 billion in the 2015-16 flu season to approximately $5.3 billion in the 2021-22 flu season (in the countries comprising the top seven markets). Recent flu seasons have shown an increase in the influenza disease burden. For the 2017-18 flu season, the Centers for Disease Control and Prevention estimates that influenza in the U.S. resulted in 48.8 million illnesses, 959,000 hospitalizations and 79,400 deaths, a dramatic increase across all categories compared to previous years.

In October 2019, we initiated a pivotal Phase 3 clinical trial of NanoFlu in older adults (65 years and older). This randomized, observer-blinded, active-controlled trial will evaluate the immunogenicity and safety of NanoFlu with its proprietary Matrix-M adjuvant, compared to a U.S.-licensed quadrivalent vaccine, Fluzone® Quadrivalent. The trial's primary objective is to demonstrate non-inferior immunogenicity as measured by hemagglutination inhibition ("HAI") titers of vaccine homologous influenza strains compared to a licensed seasonal vaccine, and to describe its safety profile. In October 2019, we completed enrollment of 2,652 healthy older adults across 19 clinical sites in the U.S. and we expect to report top-line clinical data by the end of the first quarter of 2020. Positive data will support a subsequent U.S. biologics license application ("BLA") and licensure of NanoFlu using the U.S. Food and Drug Administration's ("FDA") accelerated approval pathway.

In January 2020, we announced that the FDA granted NanoFlu Fast Track designation, which is intended for products that treat serious or life-threatening diseases or conditions and that demonstrate the potential to address unmet medical needs for such diseases or conditions. The program is designed to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that approved products can reach the market expeditiously. Specifically, Fast Track designation facilitates meetings to discuss all aspects of development to support licensure and provides the opportunity to submit sections of a BLA on a rolling basis as data become available. This permits the FDA to review modules of the BLA as they are received instead of waiting for the entire BLA submission. In addition, priority review (six-month review versus standard 10-month review) is an additional benefit that may potentially be available for NanoFlu in the future.

In June 2019, we announced that the FDA acknowledged that the accelerated approval pathway is available for NanoFlu. An accelerated approval may be granted for certain biological products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments. Such an approval will be based on adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. For seasonal influenza vaccines, the HAI antibody response is considered an acceptable surrogate marker of activity that is reasonably likely to predict clinical benefit. To be considered for accelerated approval, a BLA for a new seasonal influenza vaccine should include results from one or more well-controlled studies designed to meet immunogenicity endpoints along with a commitment to conduct confirmatory post-marketing studies of clinical effectiveness in preventing influenza.

Respiratory Syncytial Virus (RSV)

Currently, there is no approved RSV vaccine available to combat the estimated 64 million RSV infections that occur globally each year. We have identified three susceptible target populations that we believe could benefit from the development of our respiratory syncytial virus fusion (F) protein nanoparticle vaccine candidate ("RSV F Vaccine") in different formulations: (1) infants via maternal immunization, (2) older adults (60 years and older) and (3) children six months to five years old ("pediatrics"). With our current estimates of the annual global cost burden of RSV in excess of $88 billion, we believe our RSV F Vaccine represents a multi-billion dollar worldwide opportunity.

ResVax Program (Infants via Maternal Immunization)

ResVax is our adjuvanted RSV F Vaccine for infants via maternal immunization. RSV is the most common cause of lower respiratory tract infections ("LRTI") and the leading viral cause of severe lower respiratory tract disease in infants and young children worldwide. In the U.S., RSV is the leading cause of hospitalization of infants and, globally, is second only to malaria as a cause of death in children under one year of age.

Data from our Prepare trial, which was initiated in December 2015, was announced in February 2019. The Prepare trial was conducted to determine whether ResVax reduced incidence of medically significant RSV-positive LRTI in infants through a minimum of the first 90 days of life and up through the first six months of life. While these data did not meet the trial's primary efficacy endpoint, it did demonstrate efficacy against a secondary objective by reducing RSV LRTI hospitalizations in treated infants. ResVax is thus the first RSV vaccine to show efficacy in a Phase 3 clinical trial, and in addition, showed important effects against a variety of pre-specified exploratory endpoints and post-hoc analyses. This included a ~60% reduction in RSV-related severe hypoxemia and a ~74% reduction in RSV-related, radiographically-confirmed pneumonia through day 90. As in previous clinical trials, ResVax also showed favorable safety and tolerability results. In light of the fact that the trial failed to meet the primary endpoints, the FDA and European Medicines Agency ("EMA") recommended that we conduct an additional Phase 3 clinical trial to confirm efficacy. BMGF has supported the Prepare trial for ResVax through a grant of up to $89.1 million; BMGF continues to financially support our efforts to conduct certain follow-on analyses of the Phase 3 data. We are currently in discussions with multiple potential commercial partners about the opportunity to bring ResVax to market globally, including assisting us with the regulatory licensure pathways in the U.S., the European Union and other geographies.

RSV Older Adults Program

Older adults (60 years and older) are at increased risk for RSV disease due in part to immunosenescence, the age-related decline in the human immune system. RSV infection can also lead to exacerbation of underlying co-morbidities such as chronic obstructive pulmonary disease, asthma and congestive heart failure. In the U.S. alone, a reported RSV incidence rate of 5.5% in older adults would account for approximately 2.5 million infections per year. We estimate that approximately 900,000 medical interventions are caused by RSV disease in this U.S. population each year. We followed up the 2016 Phase 3 clinical trial of our RSV F Vaccine, which failed to meet its pre-specified primary or secondary efficacy objectives, with a 2017 Phase 2 clinical trial in older adults, to assess safety and immunogenicity of one and two dose regimens of our RSV F Vaccine, with and without aluminum phosphate or our proprietary Matrix-M adjuvant. Immunogenicity results from the 2017 trial indicate that both adjuvants increase the magnitude, duration and quality of the immune response versus the non-adjuvanted RSV F Vaccine. We continue to assess the development opportunities for our RSV F Vaccine in older adults.

RSV Pediatrics Program

By the age of five, essentially all children will have been exposed to RSV and will likely develop natural immunity against the virus; however, children under five remain vulnerable to RSV disease, offering a strong rationale for a pediatric vaccine that could offer enhanced protection. In 2015, we announced positive results in our Phase 1 clinical trial evaluating the safety and immunogenicity of our RSV F Vaccine in healthy children between two and six years of age. We continue to assess the development opportunities for our RSV F Vaccine for pediatrics.

Combination Seasonal Influenza/RSV F Vaccine

With the ongoing development of our NanoFlu and RSV F Vaccine, a strong rationale exists for developing a combination respiratory vaccine that is designed to protect susceptible populations against both diseases. Although testing is at an early stage, we believe that a combination vaccine against both influenza and RSV may be achievable.

Ebola Virus

Ebola virus ("EBOV") is a filovirus that produces severe, often fatal illness in humans. Within the last decade, it has produced two large outbreaks in Sub-Saharan Africa with high mortality. There are currently no licensed treatments proven to prevent EBOV, although a range of blood, immunological and drug therapies are under development.

We have developed an EBOV glycoprotein vaccine candidate ("Ebola GP Vaccine") expressed in insect cells, using our core recombinant baculovirus technology. In five separate studies, carried out in collaboration with the National Institute of Allergy and Infectious Disease, active immunization with Ebola GP Vaccine was shown to be highly immunogenic and efficacious in preventing lethal disease in non-human primates challenged with EBOV. Our 2015 Phase 1 clinical trial demonstrated that our Ebola GP Vaccine is highly immunogenic in humans, well-tolerated and, in conjunction with our proprietary Matrix-M adjuvant, demonstrated marked antigen dose-sparing and induced significant increases in neutralizing antibody titers. While we intend to advance our Ebola GP Vaccine, doing so will be dependent upon funding or a partner.

Coronavirus

Coronaviruses ("CoV"), so named for their "crown-like" appearance, are a large family of viruses that spread from animals to humans and include diseases such as Middle East Respiratory Syndrome ("MERS") and Severe Acute Respiratory Syndrome ("SARS"). Historically, we developed a vaccine candidate against MERS, a novel coronavirus first identified in 2012, as well as a vaccine candidate against SARS in 2005. In 2012, within weeks of obtaining the sequence of the circulating MERS strain, we successfully produced a vaccine candidate designed to provide protection. Our MERS candidate was based on the major surface spike protein, which we had previously identified as the antigen of choice in our work with our SARS vaccine candidate. In 2014, in collaboration with the University of Maryland, School of Medicine, we published results that showed our MERS and SARS vaccine candidates both blocked infection in laboratory studies.

Recently, a new strain of coronavirus ("COVID-19") causing pneumonia-like symptoms has emerged in China, marking the beginning of a spread of the virus across the globe. Researchers have now confirmed that the virus can spread via human-to-human transmission. There are currently no licensed treatments proven to prevent COVID-19, although a range of vaccine candidates are under development. We have successfully produced a vaccine candidate designed to provide protection against COVID-19. Using our recombinant nanoparticle technology, we have generated antigen for our initial vaccine candidate derived from the coronavirus spike (S) protein. This vaccine candidate has been engineered from the genetic sequence of COVID-19 virus and binds efficiently with the same human receptors targeted by the virus, a critical aspect for effective vaccine protection. We intend to combine our proprietary Matrix-M adjuvant into our experimental vaccine candidate to potentially provide an additional immune response. We were recently awarded initial funding from the Coalition for Epidemic Preparedness Innovations ("CEPI") to facilitate our development of a COVID-19 vaccine in preparation for potential future clinical trials. A subsequent CEPI award may be available to cover our program expenditures through Phase 1 clinical trial results.

CPLB Joint Venture

CPL Biologicals Private Limited ("CPLB"), our joint venture between Novavax and Cadila Pharmaceuticals Limited ("Cadila"), is actively developing a number of vaccine candidates in India. CPLB is owned 20% by Novavax and 80% by Cadila.

Vaccine Technology

Our recombinant protein nanoparticle vaccine technology is based on self-assembly of surface protein antigens from pathogenic organisms including viruses, bacteria or parasites. The conformations of these nanoparticles are similar but not identical to the natural structure of surface antigens of disease organisms, and lack the genetic material required for replication and therefore are not infectious. Potential immunological advantages of protein nanoparticles may be associated with the nanoparticle conformation and the presentation of key functional epitopes that are often immunologically hidden in the native pathogen. This leads to efficient recognition by the immune system's antigen presenting cells that trigger robust immune responses. Recognition of the nanoparticle vaccine's repeating protein patterns by the antigen presenting cells' toll-like receptors to stimulate innate immunity and the high purity and lack of synthetic material adds to the potential safety of recombinant nanoparticle vaccines. Protein nanoparticle vaccine technology has expanded our early-stage vaccines in development to include both virus and non-virus disease targets. Our most advanced protein nanoparticle vaccine candidate is our RSV F Vaccine, which self-assembles from our highly purified F-protein antigen.

Matrix Adjuvants

Adjuvants are predominantly used to enable a vaccine to increase the amplitude of the immune response and qualitatively change it, broadening the immune system's attack against microorganisms and allowing for effective immunization with much lower doses of antigen. Novavax AB has developed a number of adjuvant formulations, all based on our proprietary Matrix technology. These adjuvant formulations possess excellent immunostimulatory features with the ability to increase and prolong the protective benefits of vaccines.

While adjuvants based on novel, poorly characterized substances have been hampered by safety concerns and limited efficacy, Matrix adjuvants stimulate strong antibody and cell-mediated immune responses. Matrix adjuvants may allow for lower antigen doses, longer-duration immune responses and carry a lower risk for allergic reactions or other adverse events. Our Matrix technology typically induces strong cellular activation of both Th1 and Th2 types, thereby generating all classes and subclasses of antibodies, as well as potent cellular responses, including cytotoxic T lymphocytes. Our Matrix-M adjuvant provides a potent adjuvant effect that has been well-tolerated in clinical trials. We also believe that the strong immune response and opportunity to reduce the quantity of antigen dose can significantly reduce the production cost of our vaccines. This means that our Matrix-M adjuvant has the potential to be of significant value when there is inadequate vaccine manufacturing capacity during an emerging disease threat such as an influenza pandemic.

Competition in RSV and Influenza

The vaccine market is intensely competitive, characterized by rapid technological progress. Our technology is based upon utilizing the baculovirus expression system in insect cells to make recombinant vaccines. We believe this system offers many advantages when compared to other technologies and is uniquely well-suited for developing RSV and influenza vaccines, as well as vaccines against a number of other infectious diseases.

There is currently no approved RSV vaccine for sale in the world; however, a number of vaccine manufacturers, academic institutions and other organizations currenly have, or have had, programs to develop such a vaccine. These groups are developing products to prevent disease caused by RSV using a variety of technology platforms, including viral vectors, nucleic acid (RNA/DNA), live attenuated chimeric, antigens or monoclonal antibodies ("Mab") and competitive recombinant technologies. Despite the announcement of results from the Prepare trial of ResVax, we continue to believe that our RSV F vaccine candidate, which is a recombinant prefusogenic F-protein nanoparticle, is likely to be as effective as other RSV vaccine candidates or other products in development by our competitors, and may prove effective. We further believe that ResVax, our RSV vaccine program for infants via maternal immunization, is the only RSV vaccine to have ever demonstrated some degree of efficacy in a Phase 3 clinical trial. At this time, there are a number of companies and other organizations with vaccine candidates in Pbase 1 and 2 trials, including Pfizer, GlaxoSmithKline, Sanofi, Bavarian Nordic, Janssen, Moderna, Ablynx, Immunovaccine, Intravaac, Vaxart and the NIAID. Presently, the two lead Mab programs seeking to develop product candidates to prevent RSV in infants are being conducted by AstraZeneca PLC ("AstraZeneca"), and Merck. The AstraZeneca Mab, Nirsevimab (previously known as MEDI-8897), which is partnered with Sanofi Pasteur and Swedish Orphan Biovitrum AB, completed Phase 2 trials for preterm infants and is in Phase 3 trial for full-term infants. Additionally, it has obtained Breakthrough designation from the FDA. The Merck Mab MK-1654 is currenly in Phase 2 trials in preterm and full-term infants.

There are a number of companies developing and selling vaccines for seasonal influenza employing both traditional (egg-based) and new vaccine technologies (cell-based). Many seasonal influenza vaccines are currently approved and marketed, and most of these are marketed by major pharmaceutical companies that have significantly greater financial and technical resources, experience and expertise. Competition in the sale of seasonal influenza vaccines is intense. For the older adult segment, Sanofi currently supplies Fluzone-HD® and Flublok® to the majority (>60%) of U.S. older adults. Therefore, newly developed and approved products must be differentiated from existing vaccines in order to have commercial success. In order to show differentiation in the seasonal influenza market, a product may need to be more efficacious and/or be less expensive and quicker to manufacture. Many of our competitors are working on new products and new generations of current products, some by adding an adjuvant that is used to increase the immunogenicity of that product, each of which is intended to be more efficacious than currenly marketed products. Despite the significant competition and advancing technologies, some of which are similar to our own, based on our completed Phase 2 trial results, we believe that NanoFlu, our adjuvanted nanoparticle seasonal influenza product could be as efficacious as, or more so than, current products or products being developed by our competitors. However, our seasonal influenza vaccine may not prove to be efficacious or our manufacturing system may not prove to be sufficiently effective and differentiated to ensure commercial success.

In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also may depend upon our ability to show differentiation with a product that is more efficacious and/or less expensive and quicker to manufacture. Other factors affecting our competitive position include our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the lengthy period between technological conception and commercial sale.

Patents and Proprietary Rights

We generally seek patent protection for our tecbnology and product candidates in the U.S. and abroad. The patent position of biotechnology and pharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third-parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

Patent Rights; Licenses.

We have intellectual property (patents, licenses, know-how) related to our vaccines, manufacturing processes and other technologies. Currently, we have or have rights to over 400 U.S. patents and corresponding foreign patents and patent applications relating to vaccines and vaccine-related technologies.

Patents related to our VLP program include U.S. Patent No. 7,763,450, which covers, in part, the use of influenza gene sequences for high-yield production of consistent influenza VLP vaccines to protect against current and future seasonal and pandemic strains of influenza viruses. Corresponding European patent, European Patent No. 1644037 also covers this technology. U.S. Patent Nos. 8,080,255, 8,551,756, 8,506,967 and 8,592,197 are directed to methods of producing VLPs and inducing substantial immunity to an influenza virus infection by administering VLPs comprising HA and NA proteins, and our M1 protein derived from the avian influenza strain, A/Indonesia/5/05. Certain claims also encompass similar methods and compositions where the M1 protein is from a different strain of influenza virus than the influenza HA protein and the influenza NA protein. Related patent protection in Europe is provided by European Patent No. 2343084, which covers, in part, vaccine compositions containing VLPs that contain M1, HA, and NA proteins. Our VLP patent portfolio contains many other patents, including U.S. Patent Nos. 8,951,537, 8,992,939, 9,144,607, 9,050,290, 9,180,180, 9,381,239, 9,464,276, 9,474,799, and other patents in multiple ex-U.S. jurisdictions.

We also have issued patents directed to other core programs, including our RSV and influenza programs. Issued patents directed to various aspects of the RSV program include U.S. Patent Nos. 8,715,692, 9,675,685, 9,731,000, 9,717,786, 10,022,437, and 10,426,829. Additional patents in the family include EP237009 in Europe, as well as others throughout the world. Patents related to our rabies program include 9,724,405 and 10,086,065 in the U.S. and EP2635257 in Europe. Related patents have been issued in other world markets. In addition to our focus on vaccine programs, we also pursue patent protection for our Matrix Adjuvant program. Issued U.S. Patent Nos. 7,838,019, 9,205,147, 9,901,634 and 8,821,881 provide examples of patents related to our Matrix Adjuvant program.

We continue to prepare, file, and prosecute patent applications to provide broad and strong protection of our proprietary rights, including next generation applications focused on our RSV Program, our influenza nanoparticle program, and our adjuvant program.

The Federal Technology Transfer Act of 1986 and related statutory guidance encourages the dissemination of science and technology innovation. While our expired contract with the Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("HHS BARDA") provided us with the right to retain ownership in our inventions that may have arisen during performance of that contract, with respect to certain other collaborative research efforts with the U.S. government, certain developments and results that may have commercial potential are to be freely published, not treated as confidential, and we may be required to negotiate a license to developments and results in order to commercialize products. There can be no assurance that we will be able to successfully obtain any such license at a reasonable cost, or that such development and results will not be made available to our competitors on an exclusive or non-exclusive basis.

Trade Secrets.

We also rely significantly on trade secret protection and confidentiality agreements to protect our interests. It is our policy to require employees, consultants, contractors, manufacturers, collaborators and other advisors to execute confidentiality agreements upon the commencement of employment, consulting or collaborative relationships with us. We also require confidentiality agreements from any entity that is to receive confidential information from us. With respect to employees, consultants and contractors, the agreements generally provide that all inventions made by the individual while rendering services to us shall be assigned to us as our property.

Government Regulations

The development, production and marketing of biological products, which include the vaccine candidates being developed by Novavax or our collaborators, are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the U.S. and other countries. Although we focus on the U.S. regulatory process and the standards imposed by the FDA, the International Conference on Harmonisation ("ICH") and other agencies because we believe meeting U.S. and ICH standards generally allows us to satisfy regulatory agencies in other countries where we intend to do business; however, we are mindful that expectations in some venues, notably in the European Union, differ to some degree and we take proactive steps to address such differences by maintaining regular filings and correspondence and attending regular meetings with many other non-U.S. regulatory agencies. In the U.S., the development, manufacturing and marketing of human pharmaceuticals and vaccines are subject to extensive regulation under the Federal Food, Drug, and Cosmetic Act, and biological products are subject to regulation under provisions of that act and the Public Health Service Act. The FDA not only assesses the safety and efficacy of these products but it also regulates, among other things, the testing, manufacture, labeling, storage, record-keeping, advertising and promotion of such products. The process of obtaining FDA licensure for a new vaccine is costly and time-consuming.

Vaccine clinical development follows the same general regulatory pathway as drugs and other biologics. Before applying for FDA licensure to market any new vaccine candidate, we expect to first submit an investigational new drug application ("IND") that explains to the FDA, among other things, the results of preclinical toxicology testing conducted in laboratory animals, the method of manufacture, quality control tests for release, the stability of the investigational product and what we propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe to move forward with testing the vaccine candidate in humans. We must then conduct Phase 1 clinical trials and larger-scale Phase 2 and 3 clinical trials that demonstrate the safety, immunogenicity and efficacy of our vaccine candidate to the satisfaction of the FDA. Following successful completion of all three phases of clinical development, a BLA can be submitted to the FDA requesting licensure of the vaccine for marketing based on the vaccine's safety and efficacy. Similar pathways exist in Europe and other geographies.

The FDA will ouly approve a BLA if the vaccine is demonstrated to be safe, pure and potent. During the FDA's review of a BLA, the proposed manufacturing facility undergoes a pre-approval inspection during whicb the FDA examines in detail the production of the vaccine, the manufacturing facility and the quality documentation related to the vaccine. Vaccine licensure also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public. Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, the FDA typically requires Phase 4 post-marketing clinical trials for vaccines after licensure to continue gathering safety, and sometimes effectiveness/efficacy data in the indicated and additional populations.

In order to ensure continuing safety, the FDA and most other non-U.S. based regulatory agencies continue to oversee the production of vaccines even after the vaccine and manufacturing processes are approved. For example, monitoring of the vaccine and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product. Manufacturers may also be required to submit the results of their own tests for potency, safety and purity for each vaccine lot, if requested by the relevant regulatory agency. They may also be required to submit samples of each vaccine lot to the agency for testing.

In addition to obtaining FDA licensure for each product, each domestic manufacturing establishment must be registered with the FDA, is subject to FDA inspection and must comply with current Good Manufacturing Practices ("GMP") regulations. To supply products for use either in the U.S. or outside the U.S., including clinical trials, U.S. and foreign manufacturing establishments, including third-party facilities, must comply with GMP regulations and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in their home country.

In 1992, the FDA instituted regulations that allow accelerated approval of certain products that treat serious or life-threatening illnesses and provide meaningful therapeutic benefit over existing treatments based on a surrogate endpoint, versus a clinical outcome, which can take many more years to demonstrate. Surrogate endpoints, generally a laboratory measurement or other physical sign shown to have some correlation with clinical benefit, can considerably shorten the development time leading up to FDA licensure. The FDA bases its decision on whether to accept a proposed surrogate endpoint on the scientific support for that endpoint. The company developing the product is required to conduct further studies to confirm the clinical benefit in Phase 4 confirmatory efficacy trials. In June 2019, we announced that the FDA acknowledged that the accelerated approval pathway is available for NanoFlu.

In addition to regulatory approvals that must be obtained in the U.S., an investigational product is also subject to regulatory approval in other countries in which it is intended to be marketed. No such product can be marketed in a country until the regulatory authorities of that country have approved an appropriate marketing application. FDA licensure does not guarantee approval by other regulatory authorities. In addition, in many countries, the government is involved in the pricing of the product. In such cases, the pricing review period often begins after market approval is granted.

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations, including national and local regulations that govern our facility in Sweden. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payers. Third-party payers include government authorities or programs, private health insurers (including managed care plans) and other organizations. These third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective at certain prices. Adequate third-party reimbursement may not be available in certain markets to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Third-party payers may also control access to, or manage utilization of, our products with various utilization management techniques.

Within the U.S., if we obtain appropriate approval in the future to market any of our product candidates, those products could potentially be covered by various government health benefit programs as well as purchased by government agencies. The participation in such programs or the sale of products to such agencies is subject to regulation. In exchange for coverage, we may be obligated to provide rebates or offer discounts under government health programs or to government and private purchasers.

The U.S. and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, including initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act ("Healthcare Reform Act") which includes changes to the coverage and reimbursement of drug products under government health care programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act, and some modifications have been implemented. Recently, there has been considerable public and government scrutiny in the U.S. of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Within the U.S., we may be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws, for activities related to future sales of any of our product candidates that may in the future receive regulatory and marketing approval. Anti-kickback laws generally prohibit a pharmaceutical manufacturer from soliciting, offering, receiving or paying any remuneration to generate business, including the purchase, prescription or use of a particular drug. Althougb the specific provisions of these laws vary, their scope is generally broad and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices. There is therefore a possibility that our practices might be challenged under such anti-kickback laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, any claims for payment for reimbursed drugs or services to third party payers (including Medicare and Medicaid) that are false or fraudulent.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers with marketed products. The laws and regulations generally limit financial interactions between manufacturers and health care providers and/or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, any future activities (if we obtain approval and/or reimbursement from federal healthcare programs for our product candidates) could be subject to challenge.

Manufacturing

Our primary manufacturing facility is located in Uppsala, Sweden, where Novavax AB produces our Matrix adjuvants in an approximately 24,000 square foot facility comprised of GMP manufacturing, laboratory and office space.

Sources of Supply

Most of the raw materials and other supplies required in our business are generally available from established vendors in quantities adequate to meet our needs. In some cases, only one vendor has been qualified for certain of our manufacturing components. Prior to the initiation of commercial production, we plan, where feasible, to qualify multiple vendors of critical raw materials. One key vendor is GE Healthcare Company ("GEHC"), which supplies disposable components, resins, media and buffers used in our manufacturing process. GEHC and other vendors that supply our key manufacturing materials have been or will be audited for compliance with GMP standards.

An important component of our Matrix adjuvant technology is extracted from a species of soap-bark tree (*Quillaja saponaria*) that grows mainly in Chile, and we have been able to acquire high-quality quillaja extract as needed from our current suppliers.

Business Development

We strive to create sustainable value by evaluating all options, including working to obtain non-dilutive funding, similar to our agreement with BMGF related to our maternal RSV program, from both governmental and non-governmental funding sources, that would allow for:

- continued development of our vaccine candidates until such vaccines can be licensed;
- retained commercial rights in one or more major markets;
- product sales revenue; and/or
- commercialization through partners and other strategic relationships.

Employees

As of March 6, 2020, we have 165 full-time employees, of whom 24 hold M.D. or Ph.D. degrees and 51 of whom hold other advanced degrees. Of our total workforce, 127 are engaged primarily in research, development and manufacturing activities and 38 are engaged primarily in executive, business development, finance and accounting, legal and administrative functions. None of our U.S. employees are represented by labor unions or covered by collective bargaining agreements; 48 of our 49 Swedish employees are covered by typical collective bargaining agreements. We consider our relations with our employees to be good.

Availability of Information

Our website address is www.novavax.com. We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and our other filings with the Securities and Exchange Commission ("SEC"), and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after filed with or furnished to the SEC. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

We use our website (www.novavax.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included on our website (www.novavax.com) in the "Investors" or "News" sections. Accordingly, investors should monitor these portions of our website (www.novavax.com), in addition to following our press releases, SEC filings and public conference calls and webcasts.

Also available on our website is information relating to corporate governance at Novavax and our Board of Directors, including our Code of Business Conduct and Ethics. We intend to disclose on our website any future amendments to and waivers from this code that apply to our Chief Executive Officer, Principal Financial Officer, Principal Accounting Officer and Controller, and persons performing similar functions, as promptly as practicable, as may be required under applicable SEC and Nasdaq rules.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on the investor relations section of our website. Additionally, we provide notifications of news or announcements regarding press and earnings releases as part of the investor relations section of our website. The contents of our website are not part of this Annual Report on Form 10-K, or any other report we file with, or furnish to, the SEC.

Item 1A. RISK FACTORS

You should carefully consider the following risk factors in evaluating our business. A number of risk factors could cause our actual results to differ materially from those that are indicated by forward-looking statements. Some risks relate principally to our business and the industry in which we operate. Others relate principally to the securities market and ownership of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. You also should consider the other information included in this Annual Report on Form 10-K.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

We have a history of losses and our future profitability is uncertain.

Our expenses have exceeded our revenue since our formation in 1987, and our accumulated deficit at December 31, 2019 was $1.4 billion. Our revenue for the last three fiscal years was $18.7 million in 2019, $34.3 million in 2018, and $31.2 million in 2017. We may not be successful in entering into collaborations, strategic alliances and marketing, distribution or licensing arrangements with other companies or government agencies that result in significant revenue to offset our expenses. Our net losses for the last three fiscal years were $132.7 million in 2019, $184.7 million in 2018, and $183.8 million in 2017.

Historically, our losses have resulted predominantly from research and development expenses for our vaccine candidates, manufacturing-related expenses, costs related to protection of our intellectual property and other general operating expenses. Our expenses have exceeded our revenue since inception, and we believe our expenses will fluctuate over time, and may substantially increase some years, as a result of continuing research and development efforts to support our vaccine development efforts, and, if our product candidates are approved, future commercialization efforts.

Although certain specified costs associated with the development of ResVax, our RSV vaccine program for infants via maternal immunization, may be reimbursed under our contract with BMGF, we expect to continue to incur significant operating expenses and anticipate significant losses over time as we seek to:

- conduct clinical trials for RSV F Vaccine and other potential vaccine candidates;
- conduct preclinical studies for other potential vaccine candidates;
- work with third-party manufacturers to commercially scale the manufacturing process; and
- maintain, expand and protect our intellectual property portfolio.

As a result, we expect our cumulative operating losses to increase until such time, if ever, that product sales, licensing fees, royalties, milestones, contract research and other sources generate sufficient revenue to fund our operations. We may never achieve profitability and may not sustain profitability, if achieved.

We have limited financial resources and we may not be able to maintain our current level of operations or be able to fund the further development of our vaccine candidates.

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in amounts sufficient to fully fund our operations for the foreseeable future, and we will therefore use our cash resources, and expect to require additional funds, to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products.

We anticipate seeking such additional funds through a combination of public or private equity or debt financings, as well as potential collaborations, strategic alliances and marketing, distribution or licensing arrangements and non-dilutive funding from governmental and non-governmental funding entities, as well as other sources. While we may continue to apply for contracts or grants from academic institutions, non-profit organizations and governmental entities, we may not be successful. Adequate additional funding may not be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or vaccine candidates. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings also could have a material and adverse effect on the price of our common stock.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

The United Kingdom's withdrawal from the European Union could result in increased regulatory and legal complexity, which may make it more difficult for us to do business in Europe and impose additional challenges in securing regulatory approval of our product candidates in Europe.

The United Kingdom's exit from the European Union, or Brexit, and the related negotiations have caused political and economic uncertainty, including in the regulatory framework applicable to our operations and vaccine candidates in the United Kingdom and the European Union, and this uncertainty may persist for years. Brexit could, among other outcomes, disrupt the free movement of goods, services and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. For instance, preparations for Brexit have resulted in the decision to move the European Medicines Agency from the United Kingdom to the Netherlands. This transition may cause disruption or delays in granting clinical trial authorization or opinions for marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations.

The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom. It is possible that there will be increased regulatory complexities, which can disrupt the timing of our clinical trials and regulatory approvals. In addition, changes in, and legal uncertainty with regard to, national and international laws and regulations may present difficulties for our clinical and regulatory strategy. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenues and achieve and sustain profitability.

In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have, how such withdrawal will affect us, and the full extent to which our business could be adversely affected.

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Parcus Medical, LLC

Physical Address: 6423 Parkland Dr

City: Sarasota State: FL Zip Code: 34243

Telephone Number: 941-755-7965 Fax Number: 941-755-6543

Toll Free Number: _____

E-mail: licensing@anika.com Website: www.parcusmedical.com

Facility Manager: Paul Vagts

Professional qualifications and experience of facility manager: Paul Vagts is at least 21 years of age and has been employed full-time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs. Paul Vagts is currently employed by Parcus Medical, LLC, full time in a managerial level and is actively involved in and aware of the actual daily operation of the wholesale distributor. Paul Vagts is physically present at the facility during regular business hours, except when an absence has been authorized.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers
☒ Other: Specialty Distributors

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

6/3/2024

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

Name: _____
Address: _____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Michael Levitz
Print Name of Authorized Person

5/19/2021
Date

Board Use Only Date Processed:_____ Amount: $500 Check # 13517

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Wisconsin

Parent Company if any: Anika Therapeutics, Inc

Corporation Name: Parcus Medical, LLC

Mailing Address: 6455 Parkland Dr

City: Sarasota State: FL Zip: 34243

Telephone: 941-755-7965 Fax:

Contact Person: Paul Vagts

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: See Attached

Registration number issued: See Attached

Stock Exchange: ANIK

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number:

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

United States of America

State of Wisconsin

DEPARTMENT OF FINANCIAL INSTITUTIONS

Division of Corporate & Consumer Services

To All to Whom These Presents Shall Come, Greeting:

I, Patti Epstein, Administrator of the Division of Corporate and Consumer Services, Department of Financial Institutions, do hereby certify that

PARCUS MEDICAL, LLC

is a domestic corporation or a domestic limited liability company organized under the laws of this state and that its date of incorporation or organization is April 13, 2007.

I further certify that said corporation or limited liability company has, within its most recently completed report year, filed an annual report required under ss. 180.1622, 180.1921, 181.1622 or 183.0120 Wis. Stats., and that it has not filed articles of dissolution.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department on March 04, 2021.

Patti Epstein

PATTI EPSTEIN, Administrator
Division of Corporate and Consumer Services
Department of Financial Institutions

DFI/Corp/33

To validate the authenticity of this certificate

Visit this web address: http://www.wdfi.org/apps/ccs/verify/

Enter this code: **290855-924DD0ED**



Description of Operations

Parcus Medical, LLC. ("Parcus") operates as a Self-Distributing/Self- Manufacturer of 510K approved Medical Devices, Class I and Class II. Parcus devices do not contain a drug product or controlled substance.

Parcus Medical, LLC. manufacturers their own device:

Parcus Medical, LLC.
6423 Parkland Drive
Sarasota, FL 34243
FDA#: 3007319107

Parcus Medical's business hours of operation are 8:00am-5:00pm Monday-Friday Central Standard Time.

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
PARCUS MEDICAL , L.L.C.
6423 Parkland Dr
Sarasota , FL 34243
Registration Number: 3007319107
FEI Number*: 3007319107
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
Parcus Medical[6]
6423 Parkland Dr
Sarasota, FL US 34243
Owner/Operator Number: 10025454[7]

Official Correspondent:
Paul Vagts
6423 Parkland Dr
Sarasota, FL 34243
Phone: 941-7557965

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10025454&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10025454&OwnerOperatc

Page Last Updated: 02/22/2021

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10025454&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10025454&OwnerOperatc

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
PARCUS MEDICAL , L.L.C.
6423 Parkland Dr
Sarasota, FL 34243
Registration Number: 3007319107
FEI Number*: 3007319107
Status: Active
Date Of Registration Status: 2021

Owner/Operator:
Parcus Medical
6423 Parkland Dr
Sarasota, FL US 34243
Owner/Operator Number: 10025454

Official Correspondent:
Paul Vagts
6423 Parkland Dr
Sarasota, FL 34243
Phone: 941-7557965

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified MH 6/15/21

Page Last Updated: 06/14/2021
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Paul Vagts

[redacted] Riverwood Ave
Sarasota, FL 34231

[redacted]

Summary of Qualifications

Engineering Professional with eleven years combined experience in the medical field progressing from the operating room to manufacturing and government regulation both domestic and abroad. Nearly eight years of intense experience with a small, fast growing medical device manufacturer transitioning from sole Mechanical Engineer to Director of Regulatory Affairs / Quality Assurance. During this period, actively played a critical role in submitting and receiving 510(k) market clearance on many different product families as well as CE Certification and government registration in various countries throughout the world.

Education

B. S. Mechanical Engineering, Michigan Technological University, Houghton, MI

- Graduated with Honors: Cum Laude

Work Experience

Director of RA/QA 9/10 - Present

Mechanical Engineer 6/08 – 9/10

Parcus Medical, LLC Sarasota, FL

- Ensuring compliance with applicable regulations and standards for medical devices, including ISO 13485 with CMDCAS, FDA Quality Systems Regulations (QSR) 21 CFR 820, RDC #59 and the Council Directive 93/42/EEC concerning medical devices (MDD).
- Preparing device submissions and acquiring medical device (class II/IIb) clearances including 510(k), CE Marking, Canadian Device Licensing and numerous Latin American countries (including Brazil and Mexico).
- Conducting internal and site audits for the purpose of vendor qualification and/or surveillance. Identifying opportunities for improvement and/or trends and initiating preventive or corrective actions, as necessary.
- Serving as Management Representative/Administrative Representative and main point of contact for external audits (including ISO 13485, CE Marking, Technical File, Microbiology, FDA and ANVISA inspections).
- Conducting design and development deliverables (e.g. conducting design reviews, design and risk management documentation, shipping and packaging tests, sterilization validation, and any regulatory submissions).
- Maintaining document control and records management for all required company documents.
- Ensure training records are up to date and that training performed was effective.
- Interacting with manufacturing personnel in order to develop effective medical devices, while considering ease of manufacture and assembly in order to minimize the cost for the end user.
- Project manager for class II/IIb orthopedic implants, single use and reusable devices. Duties include generating, reviewing and/or approving product documentation including, but not limited to, design documentation (e.g. design plan, design inputs, etc.), drawings/prints, inspection procedures, IQ/OQ/PQ protocols and reports, benchtop and cadaveric testing reports, labeling and risk management documentation (e.g. risk management plan, risk analysis, etc.).
- Device development including design of prototypes incorporating risk analysis, manufacturing and testing of devices in benchtop or cadaveric settings as necessary.
- Generating and maintaining Design History File (DHF), Risk Management File, Device Master Record (DMR), and Technical Files as necessary.
- Reviewing, evaluating and implementing solutions to material, design and/or device related issues using Nonconformance, Customer Complaint and CAPA procedures.

- Ensure safety and quality considerations and requirements are pro-actively addressed and implemented in device production processes.
- Provide strategic assistance and mentoring as necessary.

Surgical Technician /Orthopedic Assistant 3/05 – 6/08
Community Hospital Grand Junction, CO
Allen Memorial Hospital Moab, UT

- Specialized in Cardiovascular, Orthopedic and General Surgery.
- Proactively facilitated successful surgical procedures with extensive knowledge of all instrumentation and techniques utilized.
- Evaluated and prepared recommendations for treatment of patients, ordered x-rays, CT and MRI scans, and applied/removed splints, casts and sutures.
- Wrote doctor's orders for in-patients, surgical notes, referrals to other surgeons, and consulted with patients before and following surgery.

Lodge Manager 3/04 – 8/04
Fry Canyon Lodge Fry Canyon, UT

- Applied engineering skills for maintaining a solar power system and back-up generator, pressurized water supply, and general plumbing and electrical systems.
- Managed a remote 10-room motel, café, and general store.
- Performed inventory control, cost control for all aspects of lodge, monthly projections, ordering of food and supplies, and general assurance of customer satisfaction.

Mechanical Engineering Co-op 6/01 – 12/01
C. G. Bretting Mfg Ashland, WI

- Designed and drafted detailed drawings and machine layouts using AutoCAD.
- Evaluated standard layouts and implemented ideas to achieve cost reduction, ease of manufacture and assembly, product development and improvement.
- Worked on various R & D projects with machine shop and assembly teams in order to develop a more cost effective product.

Computer skills

Windows, Microsoft Office (including Project and Visio), Bartender Automation Label Software, Adobe Professional

Professional Development

- Active participant in local RAPS Chapter's seminars and training sessions – 2014 to Present
- Attended the RAPS Convergence – October, 2015
- Attended *Current Issues in Medical Device Sterilization Seminar* provided by STERIS Isomedix Services - October, 2013.
- Attended Overview of ISO 13485:2003, the CMDRs, the MDD and JPAL – May, 2013
- Attended the FDA Small Business Regulatory Education for Industry (REdI) Conference – June, 2012
- Completed 3 day *Scientific Molding Critical Tolerances* and *Validating Medical Molding Processes* courses for developing validated cycles for injection molding of medical implants – July, 2008 and March, 2012
- Attended *The Science of Sterilization Validation Seminar* provided by Nelson Laboratories - August 2011.
- Attended medical device conferences including OrthoTec 2011, MD&M Minneapolis 2010 and MD&M Midwest 2009.
- Successfully completed ISO 9001:2008 36 Hour Lead Auditor with Medical Device Focus (ISO 13485:2003) Training – September, 2010
- Completed 4 day *Essentials* and 3 day *Advanced Part Modeling* courses for SolidWorks 3D CAD Software – 2008 and 2009.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number 001-14027

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*

32 Wiggins Avenue, Bedford, Massachusetts 01730
(Address of Principal Executive Offices) (Zip Code)

(781) 457-9000
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol*	*Name of Each Exchange on Which Registered*
Common Stock, par value $0.01 per share	ANIK	NASDAQ Global Select Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) bas filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant as of June 30, 2020, the last day of the registrant's most recently completed second fiscal quarter, was $530,765,794 computed by reference to the closing price of common stock on such date. The registrant does not have any non-voting stock outstanding.

At April 20, 2021, there were 14,366,686 shares of the registrant's common stock outstanding.

Documents Incorporated By Reference: None.

ANIKA THERAPEUTICS, INC.
TABLE OF CONTENTS FOR FORM 10-K/A

		Page
	Explanatory Note	4
Part I		
Item 1.	Business	5
Part II		
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 8.	Financial Statements and Supplementary Data	31
Item 9A.	Controls and Procedures	71
Part IV		
Item 15.	Exhibits and Financial Statement Schedules	75
Signatures		78

References in this amendment to our Annual Report on Form 10-K to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

Anika, Arthrosurface, Anika Therapeutics, Cingal, Hyaff, Monovisc, Orthovisc, Parcus Medical, Tactoset, Hyvisc and WristMotion are our registered trademarks that appear in this amendment to our Annual Report on Form 10-K/A. For convenience, these trademarks appear in this amendment to our Annual Report on Form 10-K/A without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks. This amendment to our Annual Report on Form 10-K/A also contains trademarks and trade names that are the property of other companies and licensed to us.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") to the Annual Report on Form 10-K of Anika Therapeutics, Inc. for the fiscal year ended December 31, 2020, initially filed with the Securities and Exchange Commission (the "SEC") on March 5, 2021 (the "Original Filing"), is being filed principally to correct typographical errors that resulted during the creation of the EDGAR version of the Original Filing. As the result of these errors, the Original Filing failed to include the following, all of which are included in this Amendment:

- The entire paragraph, except for the word "Research", in the section captioned "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – *Year ended December 31, 2020 compared to yeor ended December 31, 2019 – Statement of Operations Detail – Research and development.*"
- The words "a per share and tax effected basis." at the end of the first paragraph in the section captioned "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations – *Non-GAAP Financial Measures – Adjusted Net Income (Loss) and Adjusted EPS.*"
- The words "To the Board of Directors and Stockholders of Anika Therapeutics, Inc." in the beginning of the "Report of Independent Registered Public Accounting Firm" contained within the section captioned "Item 8. Financial Statements and Supplementary Data."
- The conformed signature of Deloitte & Touche LLP on the "Report of Independent Registered Public Accounting Firm" contained within the section captioned "Item 9A. Controls and Procedures." The Company received the manually signed Internal Control Report from Deloitte & Touche prior to filing the Original Filing.

In addition, this Amendment is being filed to update the explanation surrounding employees added in 2020 in the third sentence of the third full paragraph of the section captioned "Item 1. Business – Human Capital Management."

This Amendment amends the cover page and includes Items 1, 7, 8, and 9A in their entirety without change from the Original Filing except as described above. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, we are including with this Amendment new certifications of our principal executive officer and principal financial officer pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act of 2002. Accordingly, Item 15 of Part IV has also been amended to reflect the filing of these new certifications.

Except for the foregoing amended information, this Amendment does not amend or update any other information contained in the Original Filing. This Amendment does not reflect events occurring after the date of the filing of the Original Filing or modify or update those disclosures that may be affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the Original Filing and with our other filings with the SEC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This amended Annual Report on Form 10-K/A contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 concerning our business, consolidated financial condition, and results of operations. The Securities and Exchange Commission, or SEC, encourages companies to disclose forward-looking statements so that investors can better understand a company's future prospects and make informed investment decisions. Forward-looking statements are subject to risks and uncertainties, many of which are outside our control, which could cause actual results to differ materially from these statements. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements can be identified by such words as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "would," "future," "can," "could," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. All statements other than statements of historical facts included in this Annual Report regarding our strategies, prospects, financial condition, operations, costs, plans, and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements regarding expected future operating results, expectations regarding the timing and receipt of regulatory results, anticipated levels of capital expenditures, and expectations of the effect on our financial condition of claims, litigation, and governmental and regulatory proceedings.

Please refer to "Item 1A. *Risk Factors*" contained in the Original Filing for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. Any forward-looking statement made by us in this amended Annual Report on Form 10-K/A is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise.

PART I

ITEM 1. BUSINESS

Overview

Founded in 1992, Anika Therapeutics, Inc. is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Based on our collaborations with clinicians to understand what they need most to treat their patients, we develop minimally invasive products that restore active living for people around the world. We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis ("OA") pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies.

We have nearly thirty years of global expertise developing, manufacturing and commercializing products based on our hyaluronic acid, or HA, technology platform. HA is a naturally occurring polymer found throughout the body that is vital for proper joint health and tissue function. Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to multiple uses, including enabling longer residence time to support OA pain management and creating a solid form of HA called HYAFF, which is the platform for our regenerative solutions portfolio.

In early 2020, we expanded our overall technology platform and significantly enhanced our commercial infrastructure, especially in the United States, through our strategic acquisitions of Parcus Medical, LLC, or Parcus Medical, a sports medicine implant and instrumentation solutions provider focused on sports medicine and soft tissue repair, and Arthrosurface, Inc., or Arthrosurface, a company specializing in less invasive, bone preserving partial and total joint replacement solutions. Through these acquisitions, we have transformed our company. We expanded our addressable market from the over $1 billion global OA pain management market to the over $8 billion joint preservation market (which includes the faster growing sports medicine and extremities segments), improved our commercial capabilities, and expanded our product pipeline and research and development expertise in our target markets.

As we look towards the future, our business is positioned to capture value within our target market of joint preservation. We believe our success will be driven by our:

- Decades of experience in HA-based regenerative solutions and early intervention orthopedics combined under new, common management with a strong financial foundation for future investment in meaningful solutions for our customers;
- Robust network of stakeholders in our target markets to identify evolving unmet patient treatment needs;
- Prioritized investment in differentiated research and development programs;
- Expansion of our commercial capabilities globally within joint preservation;
- Opportunity to pursue strategic inorganic growth opportunities, including potential partnerships and acquisitions, leveraging our strong financial foundation and operational capabilities; and
- Energized and experienced team focused on strong values, talent, and culture.

PARCUS

Ownership Information

Applicant:

Parcus Medical, LLC.
6423 Parkland Drive
Sarasota, FL 34243
FEIN# 20-8856132
FDA#: 3007319107

State of Formation: Wisconsin

Parent Company:

Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730
FEIN# 04-3145961

State of Formation: Delaware

Anika is publicly traded on the NASDAQ (NASDAQ Symbol: ANIK)

Corporate Officers

Cheryl Blanchard, President & CEO
Business Address: 32 Wiggins Avenue, Bedford, MA 01730
Business Phone: 781-457-9200
Ownership %:0

Michael L. Levitz – EVP, Chief Financial Officer, and Treasurer
Business Address: 32 Wiggins Avenue, Bedford, MA 01730
Business Phone: 781-457-9201
Ownership %:0

Part Number	FDA Device Listing #	FDA Submission Type
10001	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10001B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10002	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10002B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10003	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10003B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10004	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10004B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10005	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10005B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10006	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10006B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10007	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10007B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10008	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10008B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10009	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10009B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10010	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10010B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10011	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10011B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10012	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10012B	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10014	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10015	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10016	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10018	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10019	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10020	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10021	D083503	K091093 (9/30/09)
10022	D083503	K091093 (9/30/09)
10023	D083503	K091093 (9/30/09)
10024	D083503	K091093 (9/30/09)
10025	D083503	K091093 (9/30/09)
10026	D083503	K091093 (9/30/09)
10027	D083503	K091093 (9/30/09)
10028	D083503	K091093 (9/30/09)
10029	D083503	K091093 (9/30/09)
10030	D083503	K091093 (9/30/09)
10031	D083503	K091093 (9/30/09)
10032	D083503	K091093 (9/30/09)
10034	D083503	K091093 (9/30/09)
10035	D083503	K091093 (9/30/09)
10036	D083503	K091093 (9/30/09)
10038	D083503	K091093 (9/30/09)

10039	D083503	K091093 (9/30/09)
10040	D083503	K091093 (9/30/09)
10163	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10164	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10165	D077865, D438099	K083619 (3/6/09), K202662 (2/22/21)
10166	D083503	K091093 (9/30/09)
10167	D083503	K091093 (9/30/09)
10168	D083503	K091093 (9/30/09)
10952	D296362	K170877 (6/2/17)
10953	D296362	K170877 (6/2/17)
10954	D296362	K170877 (6/2/17)
10995	D296362	K170877 (6/2/17)
10996	D296362	K170877 (6/2/17)
10997	D296362	K170877 (6/2/17)
10041	D057013	K083619 (3/6/09)
10042	D057013	K091093 (9/30/09)
10077	D125520	510(k) Exempt, Requires GMP
10078	D125518	510(k) Exempt, Requires GMP
10079	D125518	510(k) Exempt, Requires GMP
10080	D125518	510(k) Exempt, Requires GMP
10081	D125518	510(k) Exempt, Requires GMP
10082	D125518	510(k) Exempt, Requires GMP
10083	D125518	510(k) Exempt, Requires GMP
10084	D125518	510(k) Exempt, Requires GMP
10085	D125518	510(k) Exempt, Requires GMP
10086	D125518	510(k) Exempt, Requires GMP
10087	D125518	510(k) Exempt, Requires GMP
10088	D125518	510(k) Exempt, Requires GMP
10089	D125518	510(k) Exempt, Requires GMP
10090	D083692	510(k) Exempt, Requires GMP
10091	D083692	510(k) Exempt, Requires GMP
10092	D083692	510(k) Exempt, Requires GMP
10093	D083692	510(k) Exempt, Requires GMP
10094	D083692	510(k) Exempt, Requires GMP
10095	D083692	510(k) Exempt, Requires GMP
10096	D095073	510(k) Exempt, Requires GMP
10097	D095073	510(k) Exempt, Requires GMP
10098	D095073	510(k) Exempt, Requires GMP
10107	D083691	510(k) Exempt, Requires GMP
10110	D083692	510(k) Exempt, Requires GMP
10111	D083692	510(k) Exempt, Requires GMP
10112	D125518	510(k) Exempt, Requires GMP
10113	D125518	510(k) Exempt, Requires GMP
10114	D125518	510(k) Exempt, Requires GMP
10115	D125518	510(k) Exempt, Requires GMP
10116	D125518	510(k) Exempt, Requires GMP
10117	D125518	510(k) Exempt, Requires GMP

10118	D125518	510(k) Exempt, Requires GMP
10127	D083692	510(k) Exempt, Requires GMP
10127S	D083692	510(k) Exempt, Requires GMP
10143	D083692	510(k) Exempt, Requires GMP
10162	D083692	510(k) Exempt, Requires GMP
10173	D125518	510(k) Exempt, Requires GMP
10174	D125518	510(k) Exempt, Requires GMP
10175	D125518	510(k) Exempt, Requires GMP
10176	D125518	510(k) Exempt, Requires GMP
10177	D125518	510(k) Exempt, Requires GMP
10178	D125518	510(k) Exempt, Requires GMP
10179	D125518	510(k) Exempt, Requires GMP
10274	D057013	K083619 (3/6/09)
10275	D057013	K091093 (9/30/09)
10291	D095073	510(k) Exempt, Requires GMP
10299	D095073	510(k) Exempt, Requires GMP
10300	D095073	510(k) Exempt, Requires GMP
10301	D095073	510(k) Exempt, Requires GMP
10304	D095073	510(k) Exempt, Requires GMP
10306	D095073	510(k) Exempt, Requires GMP
10307	D095073	510(k) Exempt, Requires GMP
10308	D095073	510(k) Exempt, Requires GMP
10309	D095073	510(k) Exempt, Requires GMP
10319	D095073	510(k) Exempt, Requires GMP
10321	D095073	510(k) Exempt, Requires GMP
10372	D048479	510(k) Exempt, Requires GMP
10389	D139630	510(k) Exempt, Requires GMP
10390	D139630	510(k) Exempt, Requires GMP
10411	D139630	510(k) Exempt, Requires GMP
10421	D139630	510(k) Exempt, Requires GMP
10498	D095073	510(k) Exempt, Requires GMP
10499	D095073	510(k) Exempt, Requires GMP
10500	D083692	510(k) Exempt, Requires GMP
10512	D083692	510(k) Exempt, Requires GMP
10554	D125519	510(k) Exempt, Requires GMP
10555	D125519	510(k) Exempt, Requires GMP
10556	D125519	510(k) Exempt, Requires GMP
10559	D181966	510(k) Exempt, Requires GMP
10613U	D125518	510(k) Exempt, Requires GMP
10614U	D095073	510(k) Exempt, Requires GMP
10807	D139630	510(k) Exempt, Requires GMP
10838	D253232	510(k) Exempt, Requires GMP
11002	D150792	510(k) Exempt, Requires GMP
11016	D125518	510(k) Exempt, Requires GMP
11016U	D125518	510(k) Exempt, Requires GMP
11017	D125518	510(k) Exempt, Requires GMP
11017U	D125518	510(k) Exempt, Requires GMP

11018	D125518	510(k) Exempt, Requires GMP
11018U	D125518	510(k) Exempt, Requires GMP
11019	D125518	510(k) Exempt, Requires GMP
11019U	D125518	510(k) Exempt, Requires GMP
11277	D048479	510(k) Exempt, Requires GMP
11338	D125518	510(k) Exempt, Requires GMP
20009	D150792	510(k) Exempt, Requires GMP
20010	D057014	K083619 (3/6/09)
20015	D150792	510(k) Exempt, Requires GMP
20018	D125520	510(k) Exempt, Requires GMP
20019	D125520	510(k) Exempt, Requires GMP
20021	D083692	510(k) Exempt, Requires GMP
20098	D150792	510(k) Exempt, Requires GMP
20155	D150792	510(k) Exempt, Requires GMP
10251	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10251T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10252	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10252T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10257	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10257T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10258	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10258T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10284	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10284T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10353	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10353T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10356	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10356T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10358	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10358T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10408	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10408T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
10410	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)

10410T	D077883, D438097	K090075 (3/6/09) K201083 (7/23/20)
11028	D083503	K091094 (9/30/09)
11028T	D083503	K091094 (9/30/09)
11029	D083503	K091094 (9/30/09)
11029T	D083503	K091094 (9/30/09)
11030	D083503	K091094 (9/30/09)
11030T	D083503	K091094 (9/30/09)
10253	D083504	K091094 (9/30/09)
10253T	D083504	K091094 (9/30/09)
10254	D083504	K091094 (9/30/09)
10254T	D083504	K091094 (9/30/09)
10263	D083504	K091094 (9/30/09)
10263T	D083504	K091094 (9/30/09)
10264	D083504	K091094 (9/30/09)
10264T	D083504	K091094 (9/30/09)
10324	D083504	K091094 (9/30/09)
10324T	D083504	K091094 (9/30/09)
10325	D083504	K091094 (9/30/09)
10325T	D083504	K091094 (9/30/09)
10409	D083504	K091094 (9/30/09)
10409T	D083504	K091094 (9/30/09)
11026	D083504	K091094 (9/30/09)
11026T	D083504	K091094 (9/30/09)
11027	D083504	K091094 (9/30/09)
11027T	D083504	K091094 (9/30/09)
11084	D083504	K091094 (9/30/09)
11084T	D083504	K091094 (9/30/09)
11085	D083504	K091094 (9/30/09)
11085T	D083504	K091094 (9/30/09)
10425	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10425T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10426	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10426T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10427	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10427T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10428	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10428T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10429	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10429T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)

10430	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10430T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10431	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10431T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10432	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10432T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10433	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10433T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10434	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10434T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10435	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10435T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10436	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10436T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10437	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10437T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10438	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10438T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10439	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10439T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10440	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10440T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10442T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10443	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10443T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10472	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10472T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)

10473	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10473T	D130993, D438097	K111000 (7/28/11), K201083 (7/23/20)
10511	D150783	K120942 (4/20/12)
10511T	D150783	K120942 (4/20/12)
10517	D150783	K120942 (4/20/12)
10517T	D150783	K120942 (4/20/12)
10518	D150783	K120942 (4/20/12)
10518T	D150783	K120942 (4/20/12)
10521	D150783	K120942 (4/20/12)
10521T	D150783	K120942 (4/20/12)
10522	D150783	K120942 (4/20/12)
10522T	D150783	K120942 (4/20/12)
10523	D150783	K120942 (4/20/12)
10523T	D150783	K120942 (4/20/12)
10524	D150783	K120942 (4/20/12)
10524T	D150783	K120942 (4/20/12)
10525	D150783	K120942 (4/20/12)
10525T	D150783	K120942 (4/20/12)
11003	D150783	K120942 (4/20/12)
11003T	D150783	K120942 (4/20/12)
11004	D150783	K120942 (4/20/12)
11004T	D150783	K120942 (4/20/12)
11005	D150783	K120942 (4/20/12)
11005T	D150783	K120942 (4/20/12)
11081	D150783	K120942 (4/20/12)
11081T	D150783	K120942 (4/20/12)
11082	D150783	K120942 (4/20/12)
11082T	D150783	K120942 (4/20/12)
11083	D150783	K120942 (4/20/12)
11083T	D150783	K120942 (4/20/12)
10915	D294209	K170327 (3/30/2017)
10918	D294209	K170327 (3/30/2017)
10919	D294209	K170327 (3/30/2017)
10956	D294209	K170327 (3/30/2017)
10957	D294209	K170327 (3/30/2017)
10958	D294209	K170327 (3/30/2017)
11165	D294209	K170327 (3/30/2017)
11166	D294209	K170327 (3/30/2017)
11167	D294209	K170327 (3/30/2017)

11168	D294209	K170327 (3/30/2017)
11169	D294209	K170327 (3/30/2017)
11170	D294209	K170327 (3/30/2017)
11259	D294209	K170327 (3/30/2017) RA0046
11260	D294209	K170327 (3/30/2017) RA0046
11261	D294209	K170327 (3/30/2017) RA0046
11262	D294209	K170327 (3/30/2017) RA0046
11263	D294209	K170327 (3/30/2017) RA0046
11264	D294209	K170327 (3/30/2017) RA0046
11283	D150783	K120942 (4/20/12)
11284	D150783	K120942 (4/20/12)
11285	D150783	K120942 (4/20/12)
11286	D150783	K120942 (4/20/12)
11287	D150783	K120942 (4/20/12)
11308	D150783	K120942 (4/20/12)
10222	D048479	510(k) Exempt, Requires GMP
10277	D048479	510(k) Exempt, Requires GMP
10609	D048479	510(k) Exempt, Requires GMP
10338	D125519	510(k) Exempt, Requires GMP
10999	D125519	510(k) Exempt, Requires GMP
11092	D125519	510(k) Exempt, Requires GMP
11093	D125519	510(k) Exempt, Requires GMP
11000U	D125518	510(k) Exempt, Requires GMP
11000	D125518	510(k) Exempt, Requires GMP
10129	D270020	510(k) Exempt, Requires GMP
10966	D298615	510(k) Exempt, Requires GMP
10940	D134942	510(k) Exempt, Requires GMP
10842	D322853	510(k) Exempt, Requires GMP
11010	D298616	510(k) Exempt, Requires GMP
11011	D298617	510(k) Exempt, Requires GMP
11012	D298617	510(k) Exempt, Requires GMP
10980	D134942	510(k) Exempt, Requires GMP
10983	D134942	510(k) Exempt, Requires GMP
10986	D134942	510(k) Exempt, Requires GMP
10989	D134942	510(k) Exempt, Requires GMP

11172	D125519	510(k) Exempt, Requires GMP
11139	D048479	510(k) Exempt, Requires GMP
20016	D083691	510(k) Exempt, Requires GMP
10702	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10703	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10704	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10705	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10706	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10707	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10708	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10709	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10710	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10711	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10712	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10713	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10714	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10715	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10716	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10717	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10718	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10719	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10720	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10721	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10722	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10723	D212813, D438098	K133757 (2/4/14), K202259 (10/28/20)
10787	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)
10788	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)
10789	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)

10790	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)
10791	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)
10792	D257939, D438098	K152711 (12/10/15), K202259 (10/28/20)
11136	D257939, D438098	RA0043, CSVR 0038, K202259 (10/28/20)
11183	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
11183SB	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
11184	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
11185SB	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
11185	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
11267DSB	D370637, D438098	K192750 (1/16/20), K202259 (10/28/20)
10972	D281493, D438098	K162198 (11/18/16), K202259 (10/28/20)
10973	D281493, D438098	K162198 (11/18/16), K202259 (10/28/20)
10974	D281493, D438098	K162198 (11/18/16), K202259 (10/28/20)
11157	D343316, D438098	K183331 (2/7/19), K202259 (10/28/20)
11160	D343316, D438098	K183331 (2/7/19), K202259 (10/28/20)
11200	D348158, D438098	K190375 (4/24/19), K202259 (10/28/20)
11223	D358613, D438098	K191783 (10/9/19), K202259 (10/28/20)
11224	D363824	K192964 (11/22/19)
11225	D358613, D438098	K191783 (10/9/19), K202259 (10/28/20)
11226	D363824	K192964 (11/22/19)
10057	D083692	K090923 (6/30/09)
11216	D125518	510(k) Exempt, Requires GMP
11152	D125518	510(k) Exempt, Requires GMP
11152U	D125518	510(k) Exempt, Requires GMP
11152SB	D125518	510(k) Exempt, Requires GMP
11152SBU	D125518	510(k) Exempt, Requires GMP
11152SBU	D125518	510(k) Exempt, Requires GMP
11272	D150792	510(k) Exempt, Requires GMP
11220	D125518	510(k) Exempt, Requires GMP
11361	D125518	510(k) Exempt, Requires GMP
11362	D404265	510(k) Exempt, Requires GMP
11035	D125518	510(k) Exempt, Requires GMP

11036	D125518	510(k) Exempt, Requires GMP
11037	D125518	510(k) Exempt, Requires GMP
11038	D125518	510(k) Exempt, Requires GMP
11039	D125518	510(k) Exempt, Requires GMP
11040	D125518	510(k) Exempt, Requires GMP
11050	D125518	510(k) Exempt, Requires GMP
11330	D057006	Exempt
10323	D125504	K102326 (11/15/10)
10323T	D125504	K102326 (11/15/10)
10407	D125504	K102326 (11/15/10)
10407T	D125504	K102326 (11/15/10)
10312	D150781, D370641	K102162 (11/10/10), K113730 (1/17/12), K193295 (1/23/20)
10312H	D150781, D370641	K102162 (11/10/10), K113730 (1/17/12), K193295 (1/23/20)
10313	D150781	K102162 (11/10/10), K113730 (1/17/12)
10314	D150781	K102162 (11/10/10), K113730 (1/17/12)
10315	D150781, D370641	K102162 (11/10/10), K113730 (1/17/12), K193295 (1/23/20)
11321	D370641	K193295 (1/23/20)
11321H	D370641	K193295 (1/23/20)
10994	D150781	K102162 (11/10/10), K113730 (1/17/12)
11175	D150781	K102162 (11/10/10), K113730 (1/17/12)
11176	D150781	K102162 (11/10/10), K113730 (1/17/12)
10354, 10354T	D150781	K102162 (11/10/10)
10565	D183936	K122805 (2/5/13)
10566	D183936	K122805 (2/5/13)
10588	D183936	K122805 (2/5/13)
10820	D183936	K122805 (2/5/13)
11034	D183936	K122805 (2/5/13)
11148	D183936	K122805 (2/5/13)
11150	D183936	K122805 (2/5/13)
11151	D183936	K122805 (2/5/13)
11031	D183936	K122805 (2/5/13)
11288	D183936	K122805 (2/5/13)
11289	D183936	K122805 (2/5/13)
11297	D183936	K122805 (2/5/13)
11339	D125504	K102326 (11/15/10)
[redacted]		
10483	D057009	K113730 (1/17/12)
10487	D057009	K113730 (1/17/12)

10330	D150792	510(k) Exempt, Requires GMP
10446	D150792	510(k) Exempt, Requires GMP
10446H	D150792	510(k) Exempt, Requires GMP
10591	D150792	510(k) Exempt, Requires GMP
10823	D150792	510(k) Exempt, Requires GMP
10924	D150792	510(k) Exempt, Requires GMP
10924H	D150792	510(k) Exempt, Requires GMP
10405	D150792	510(k) Exempt, Requires GMP
10406	D150792	510(k) Exempt, Requires GMP
10771	D150792	510(k) Exempt, Requires GMP
10771H	D150792	510(k) Exempt, Requires GMP
10933	D150792	510(k) Exempt, Requires GMP
10933H	D150792	510(k) Exempt, Requires GMP
10333U	D125518	510(k) Exempt, Requires GMP
10359U	D125518	510(k) Exempt, Requires GMP
10363U	D125518	510(k) Exempt, Requires GMP
10444U	D125518	510(k) Exempt, Requires GMP
10445U	D125518	510(k) Exempt, Requires GMP
10482U	D125518	510(k) Exempt, Requires GMP
10505U	D125518	510(k) Exempt, Requires GMP
10507U	D125518	510(k) Exempt, Requires GMP
10537U	D125518	510(k) Exempt, Requires GMP
10538U	D125518	510(k) Exempt, Requires GMP
10540U	D125518	510(k) Exempt, Requires GMP
10541U	D125518	510(k) Exempt, Requires GMP
10589U	D125518	510(k) Exempt, Requires GMP
10590U	D125518	510(k) Exempt, Requires GMP
10615U	D125518	510(k) Exempt, Requires GMP
10615HU	D125518	510(k) Exempt, Requires GMP
10873U	D125518	510(k) Exempt, Requires GMP
10874U	D125518	510(k) Exempt, Requires GMP
10333	D125518	510(k) Exempt, Requires GMP
10359	D125518	510(k) Exempt, Requires GMP
10363	D125518	510(k) Exempt, Requires GMP
10444	D125518	510(k) Exempt, Requires GMP
10445	D125518	510(k) Exempt, Requires GMP
10482	D125518	510(k) Exempt, Requires GMP
10505	D125518	510(k) Exempt, Requires GMP
10507	D125518	510(k) Exempt, Requires GMP
11152	D125518	510(k) Exempt, Requires GMP
10397	D095073	510(k) Exempt, Requires GMP
10365	D125519	510(k) Exempt, Requires GMP
10610	D125519	510(k) Exempt, Requires GMP
10611	D125519	510(k) Exempt, Requires GMP
10612	D125519	510(k) Exempt, Requires GMP

10761	D125520	510(k) Exempt, Requires GMP
10760	D125520	510(k) Exempt, Requires GMP
11241	D150792	510(k) Exempt, Requires GMP
20190	D125520	510(k) Exempt, Requires GMP
20191	D125520	510(k) Exempt, Requires GMP
20032	D261945	Class III - Rule 8
20032S	D261945	Class III - Rule 8
20033	D125521	Class III - Rule 8
20033S	D125521	Class III - Rule 8
20034	D261945	Class III - Rule 8
20034S	D261945	Class III - Rule 8
20035	D261945	Class III - Rule 8
20035S	D261945	Class III - Rule 8
20036	D125521	Class III - Rule 8
20036S	D125521	Class III - Rule 8
20037	D125521	Class III - Rule 8
20037S	D125521	Class III - Rule 8
20038	D125521	Class III - Rule 8
20038S	D125521	Class III - Rule 8
20039	D125521	Class III - Rule 8
20039S	D125521	Class III - Rule 8
20040	D125521	Class III - Rule 8
20040S	D125521	Class III - Rule 8
20041	D125521	Class III - Rule 8
20041S	D125521	Class III - Rule 8
20042	D261945	Class III - Rule 8
20042S	D261945	Class III - Rule 8
20043	D125521	Class III - Rule 8
20043S	D125521	Class III - Rule 8
20044	D261945	Class III - Rule 8
20044S	D261945	Class III - Rule 8
20045	D125521	Class III - Rule 8
20045S	D125521	Class III - Rule 8
20046	D125521	Class III - Rule 8
20046S	D125521	Class III - Rule 8
20047	D125521	Class III - Rule 8
20047S	D125521	Class III - Rule 8
20048	D125521	Class III - Rule 8
20048S	D125521	Class III - Rule 8
20049	D125521	Class III - Rule 8
20049S	D125521	Class III - Rule 8
20050	D125521	Class III - Rule 8
20050S	D125521	Class III - Rule 8
20051	D125521	Class III - Rule 8
20051S	D125521	Class III - Rule 8
20052	D125521	Class III - Rule 8
20052S	D125521	Class III - Rule 8

20053	D125521	Class III - Rule 8
20053S	D125521	Class III - Rule 8
20054	D125521	Class III - Rule 8
20054S	D125521	Class III - Rule 8
20055	D125521	Class III - Rule 8
20055S	D125521	Class III - Rule 8
20056	D125521	Class III - Rule 8
20056S	D125521	Class III - Rule 8
20057	D125521	Class III - Rule 8
20057S	D125521	Class III - Rule 8
20058	D125521	Class III - Rule 8
20058S	D125521	Class III - Rule 8
20059	D125521	Class III - Rule 8
20059S	D125521	Class III - Rule 8
20060	D125521	Class III - Rule 8
20174	D261945	K153307 (5/10/10)
20174S	D261945	K153307 (5/10/10)
20175 - deleted	D125521	Class III - Rule 8
20175S - deleted	D125521	Class III - Rule 8
20176 - deleted	D125521	Class III - Rule 8
20176S - deleted	D125521	Class III - Rule 8
20177 - deleted	D125521	Class III - Rule 8
20177S - deleted	D125521	Class III - Rule 8
20188	D125521	K100006 (5/10/10)
20188S	D125521	K100006 (5/10/10)
20189	D364832	K190817
20189S	D364832	K190817
10796	D348154	K183501 (3/15/19)
10796T	D348154	K183501 (3/15/19)
10797	D348154	K183501 (3/15/19)
10797T	D348154	K183501 (3/15/19)
10798	D348154	K183501 (3/15/19)
10798T	D348154	K183501 (3/15/19)
11097	D348154	K183501 (3/15/19)
11097T	D348154	K183501 (3/15/19)
11098	D348154	K183501 (3/15/19)
11098T	D348154	K183501 (3/15/19)
11099	D348154	K183501 (3/15/19)
11099T	D348154	K183501 (3/15/19)
10927	D348154	K183501 (3/15/19)
10927T	D348154	K183501 (3/15/19)
10928	D348154	K183501 (3/15/19)
10928T	D348154	K183501 (3/15/19)
11122	D348154	K183501 (3/15/19)

11122T	D348154	K183501 (3/15/19)
11123	D348154	K183501 (3/15/19)
11123T	D348154	K183501 (3/15/19)
11124	D348154	K183501 (3/15/19)
11124T	D348154	K183501 (3/15/19)
11125	D348154	K183501 (3/15/19)
11125T	D348154	K183501 (3/15/19)
11126	D348154	K183501 (3/15/19)
11126T	D348154	K183501 (3/15/19)
11127	D348154	K183501 (3/15/19)
11127T	D348154	K183501 (3/15/19)
11355	D348154	K183501 (3/15/19)
11356	D348154	K183501 (3/15/19)
11357	D348154	K183501 (3/15/19)
11358	D348154	K183501 (3/15/19)
11359	D348154	K183501 (3/15/19)
11360	D348154	K183501 (3/15/19)
10802	D363823	K192824 (11/2/19)
10803	D363823	K192824 (11/2/19)
10804	D363823	K192824 (11/2/19)
11436	D435077	K193497 (cleared 5-Jan-21)
11437	D435077	K193497 (cleared 5-Jan-21)
11438	D435077	K193497 (cleared 5-Jan-21)
11439	D435077	K193497 (cleared 5-Jan-21)
11440	D435077	K193497 (cleared 5-Jan-21)
11441	D435077	K193497 (cleared 5-Jan-21)
11442	D435077	K193497 (cleared 5-Jan-21)
11443	D435077	K193497 (cleared 5-Jan-21)
20016	**D083691**	**510(k) Exempt, Requires GMP**

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and non-transferable checks only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Pharming Healthcare, Inc.

Physical Address: 10 Independence Blvd., Suite 401

City: Warren State: NJ Zip Code: 07059

Telephone Number: 844-474-2764 Fax Number: 908-524-0388

Toll Free Number: N/A

E-mail: licensing@pharming.com Website: www.pharming.com

Facility Manager: Matthew P. Holley

Professional qualifications and experience of facility manager: See Attachment B

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☒ Other: Distributors

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate) N/A

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration) See Attachment C

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: See Attachment F
Address:

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Matt Holley (Mar 19, 2021 18:09 EDT)

Original Signature of Person Authorized to Submit Application, no copies or stamps

Matthew P. Holley
Print Name of Authorized Person

Mar 19, 2021
Date

Board Use Only	Date Processed:_____	Amount: $525.00 (CC)

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Pharming Group, N.V.

Corporation Name: Pharming Healthcare, Inc.

Mailing Address: 10 Independence Blvd., Suite 401

City: Warren State: NJ Zip: 07059

Telephone: 844-474-2764 Fax: 908-524-0388

Contact Person: Matthew P. Holley

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 1988

Registration number issued: 001-39822

Stock Exchange: NASDAQ

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment E

List of officers and directors. See Attachment D

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report_____

Commission file number 001-39822

Pharming Group N.V.
(Exact name of registrant as specified in its charter)

The Netherlands	2834	Not applicable
(Jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(Translation of Registrant's name into English)

Darwinweg 24
2333 CR Leiden
The Netherlands
Tel: +31 (0)71 5247 400
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Pharming Healthcare Inc.
10 Independence Blvd, 4th Floor
Warren, New Jersey 7059
+1 908 524 0888
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing ten ordinary shares, nominal value EUR 0.01 per share	PHAR	The Nasdaq Stock Market LLC
Ordinary shares, nominal value EUR 0.01 per share*		The Nasdaq Stock Market LLC*

Securities registered or to be registered pursuant to Section 12(g) of the Act. None

1155

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0742716

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notic prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

10 INDEPENDENCE BLVD, STE 401 WARREN, NJ 07059-

Reg. No.
5005213

PHARMING HEALTHCARE, INC.
10 INDEPENDENCE BLVD, STE 401
WARREN, NJ 07059-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 1/11/2021

Registration Number: 5005213 **Registered as:** Manufacturer and Wholesale

Parent Company Name: PHARMING HEALTHCARE, INC.

Trade Name:

Original Issue Date: 05/11/2017 **Expiration Date:** 01/31/2022

Current Issue Date: 12/18/2020

Disciplines: No

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0738341

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

10 INDEPENDENCE BLVD, STE 401 WARREN, NJ 07059-

Reg. No.
5005213

PHARMING HEALTHCARE, INC.
10 INDEPENDENCE BLVD, STE 401
WARREN, NJ 07059-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2021 –exp.

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 11/25/2020

Registration Number: 5005213 **Registered as:** Manufacturer and Wholesale

Parent Company Name: PHARMING HEALTHCARE, INC.

Trade Name:

Original Issue Date: 05/11/2017 **Expiration Date:** 01/31/2021

Current Issue Date: 01/07/2020

Disciplines: No

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "PHARMING HEALTHCARE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF INCORPORATION, FILED THE SEVENTH DAY OF JANUARY, A.D. 1998, AT 10 O`CLOCK A.M.

CERTIFICATE OF CHANGE OF REGISTERED AGENT, FILED THE SIXTEENTH DAY OF JUNE, A.D. 2004, AT 8:17 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID CORPORATION, "PHARMING HEALTHCARE, INC.".

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2842756 8310

SR# 20210973806

Authentication: 202776181

Date: 03-19-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment D

Corporate Officer and Director Information

Pharming Healthcare, Inc.

Corporate Officers:

Jeroen Wakkerman *Chief Executive Officer*

Anne-Marie de Groot - Kop
Chief Ethics & Compliance Officer

Stephen S. Toor
Chief Commercial Officer and President & General Manager

Board Structure

Until December 11, 2020, we had a two-tier board structure consisting of a board of management (bestuur) and a separate board of supervisory directors (raad van commissarissen). In connection with the listing of our ADSs on Nasdaq as contemplated by this prospectus, we converted our two-tier board structure into a one-tier board structure, with a single board of directors consisting of executive directors and non-executive directors, pursuant to a deed of amendment to our articles of association. This deed of amendment was executed on December 11, 2020, shortly before the listing of our ADSs on Nasdaq. We refer to this reorganization in this prospectus as the "corporate reorganization". Our Chief Executive Officer serves as our executive director.

Our management team is comprised of our managing directors together with our executive officers. Our management team is comprised of our executive directors and our executive officers and be referred to as the Executive Committee.

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors, including their ages, as of December 31, 2020. Our executive directors are also executive officers.

Name	Age	Position(s)	Term Expiring
Executive Directors:			
Sijmen de Vries, MD MBA	61	Chief Executive Officer	2021
Executive Officers:			
Jeroen Wakkerman	51	Chief Financial Officer	n/a
Bruno M.L. Giannetti, MD PhD	68	Chief Medical Officer	2021
Anne-Marie de Groot	39	Chief Ethics & Compliance Officer	n/a
Mireille Sanders, MSc	51	Chief Operations Officer	n/a
Stephen Toor	49	Chief Commercial Officer and GM Americas	n/a
Non-Executive Directors:			
Paul Sekhri	62	Chairperson	2023
Deborah Jorn, MBA (1)(2)	62	Vice Chairperson	2023
J. Barrie Ward, PhD (2)(3)	81	Director	2021
Aad de Winter, LLM (1)(3)	67	Director	2021
Barbara Yanni (1)	66	Director	2024
Mark Pykett	56	Director	2024

(1) Member of the Audit Committee
(2) Member of the Remuneration Committee
(3) Member of the Corporate Governance Committee

Executive Directors

Sijmen de Vries, MD MBA. Dr. De Vries has been our Chief Executive Officer since 2008 and he has also served in the capacity of interim Chief Financial Officer from May 2020 through November 16, 2020, upon the commencement of Mr. Wakkerman's tenure as Chief Financial Officer. Prior to joining Pharming, Dr. De Vries was the CEO of 4-Antibody and Morphochem AG. Dr. De Vries also held senior business and commercial positions at Novartis, Novartis Ophthalmics and at SmithKline Beecham Pharmaceuticals plc. Dr. De Vries holds an MD degree from the University of Amsterdam and an MBA in General Management from Ashridge Management College (UK). Dr. De Vries is also a non-executive director of Midatech Pharma plc.

Executive Officers

Jeroen Wakkerman. Mr. Wakkerman has been our Chief Financial Officer since November 2020. From 2015 to 2020, Mr. Wakkerman served as chief financial officer of Nutreco N.V., a global leader in animal nutrition and aquafeed. Prior to that, Jeroen served as chief financial officer of SHV Energy N.V., as finance director at Calor

[redacted]

From: edrls@fda.hhs.gov [mailto:edrls@fda.hhs.gov]
Sent: Tuesday, February 21, 2017 10:07 AM
To: Matthew Holley <M.Holley@pharming.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 21-FEB-2017
Labeler DUNS: 080551135
Labeler Name: Pharming Healthcare Inc.
Labeler Code: 71274

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

National Drug Code Directory

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

Current through March 25, 2021

You have searched Finished drug products

Search Results: '71274'

Back to Search Page | Search Again

CSV Excel

Search for text in the table:

Display 50 records per page

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Ruconest	71274-350-02	2100 U/1	INJECTION, POWDER, FOR SOLUTION	INTRAVENOUS	BLA125495	Pharming Healthcare Inc	71274-350	c1 esterase inhibitor recombinant	CONESTAT ALFA	HUMAN PRESCRIPTION DRUG	04/01/2018	N/A	BLA	1 VIAL, SINGLE-USE in 1 CARTON (71274-350-02) > 1 INJECTION, POWDER, FOR SOLUTION in 1 VIAL, SINGLE-USE (71274-350-01)	N/A

Previous 1 Next

Showing 1 to 1 of 1 entries

√ verified
M. H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 41434147

Application/License No. _____

Pharming Healthcare, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *10 Independence Blvd., Suite 401, Warren, NJ 07059* (Address of Applicant/Principal), as PRINCIPAL, and Platte River Insurance Company (Surety Company), a corporation organized under the laws of the state of Nebraska (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1600 Aspen Commons, Suite 300, Middleton, WI 53562 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 6, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 6th day of April, 20 21.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Tracy Krause, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

PLATTE RIVER INSURANCE COMPANY
POWER OF ATTORNEY

41434149

KNOW ALL MEN BY THESE PRESENTS, That the **PLATTE RIVER INSURANCE COMPANY**, a corporation of the State of Nebraska, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

---RICHARD F. KEKULA; MIKE MOORE; KIM SCHWENN; TRAVIS SCHREIBER; TRACY KRAUSE; KENTON ARPS---
---------MICHELLE MCLANE NOERENBERG; LACEY ENDRES; DANIELLE NOBLE; DAVID J. RUDNIK ---------
----------CHELSEA A. BREMER; JANET L. RUDNIK; PAMELA L. RONSKI ----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

----------ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **PLATTE RIVER INSURANCE COMPANY** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

IN WITNESS WHEREOF, the **PLATTE RIVER INSURANCE COMPANY** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 3rd day of May, 2017.

Attest:

John E. Rzepinski
Vice President, Treasurer & CFO

Suzanne M. Broadbent
Assistant Secretary

PLATTE RIVER INSURANCE COMPANY
CORPORATE SEAL
NEBRASKA

PLATTE RIVER INSURANCE COMPANY

Stephen J. Sills
CEO & President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 3rd day of May, 2017 before me personally came Stephen J. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is President of **PLATTE RIVER INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE NOTARY PUBLIC STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **PLATTE RIVER INSURANCE COMPANY**, a Nebraska Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 6th day of April, 20 21.

SEAL

Antonio Celii
General Counsel, Vice President & Secretary

THIS DOCUMENT IS NOT VALID UNLESS PRINTED ON GREEN SHADED BACKGROUND WITH A RED SERIAL NUMBER IN THE UPPER RIGHT HAND CORNER. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450. PR-POA (Rev. 10-2017)

Attachment F

Nature of Business

Pharming Healthcare, Inc. (Pharming) is a prescription drug manufacturer. Pharming is wholly-owned by Pharming Group, N.V. a publicly traded company. Pharming utilizes a contract manufacturer to produce its product and a third party logistics provider to warehouse and distribute. Accordingly, Pharming will never physically handle, store, or maintain any prescription drugs at its location. Provided below is the contact information for the third party logistics provider and contract manufacturer:

Third Party Logistics Provider:

Cardinal Health 105, Inc.
d/b/a Specialty Pharmaceutical Services
501 Mason Road, Suite 200
LaVergne, TN 37086

Contract Manufacturer:

BioConnection B.V.
Kloosterstraat 9, 5349 AB Oss, Netherlands

As confirmed by your office, an applicant who is wholly-owned by a publicly traded company is not required to provide a surety bond.

Attachment B

Facility Manger's Resume

Matthew Holley

[redacted] Woodland Drive
Princeton, New Jersey 08540
[redacted]

Jan 2017 – Present **Pharming Healthcare, Inc.** **Bridgewater, New Jersey**

General Counsel

Experience **Meda Pharmaceuticals, Inc.**

2014 – Jan 2017 Vice President and General Counsel **Somerset, New Jersey**

2012 – 2014 General Counsel **Somerset, New Jersey**

I direct legal and compliance programs for the U.S. subsidiaries of Meda AG, of Solna, Sweden, as well as supporting projects in Canada, Europe and Australia. The U.S. subsidiaries have approximately 570 employees in sales, marketing, manufacturing and various support roles. Our U.S. products include over 30 branded prescription drugs, and (through subsidiaries) generics, over-the-counter products, cosmetics and dietary supplements.

My primary functions include directing:

- prosecution of "Paragraph IV" patent cases and trademark litigation, including five Delaware federal court cases, as well as Canadian counterpart litigation;

- defense of over 5,000 failure-to-warn product liability cases;

- negotiation and drafting of patent and trademark and license agreements, as well as authorized generic marketing agreements;

- negotiating, documenting and assisting in the implementation of contract manufacturing, quality and associated agreements for inbound API, process and finished product manufacturing and outbound finished product manufacturing;

- equipment, consultant, software, data, and other service contract negotiation, drafting, filing and responsible party systems;

- commercial dispute resolution (including mediation, arbitrations and litigations); and

- employee matters.

My daily duties also regularly include regulatory matters regarding FDA, as well as FTC and other agencies. I review labeling and promotional materials and programs for FDA, FTC and CMS compliance. I often arrange for specialized legal and regulatory expertise to support development projects, including OTC switch projects. The Internal Audit function reports to me and I work on the development of the audit plan. I also support financial accounting processes and internal controls with policy development.

Particular projects have included a key role in presenting the company for sale through the investment banking process, defense of a National Advertising Division challenge of marketing claims; California consumer protection litigation, Proposition 65 allegation defense; bringing claims to enforce insurance coverage; advising on product life cycle decisions; product acquisition due diligence; divestiture of assets; patent and trademark portfolio transparency.

I have developed strong relationships across the company, which has fostered a more transparent, trusting and responsive approach to compliance with legal requirements, as well as adoption of practices that promote efficiency and equivalence across risks and resource allocation. My scope of responsibility in the company has continually been expanded, with promotion to General Counsel and then to Vice President.

2011 – 2012 Corporate Compliance Officer **Marietta, Georgia / Somerset, New Jersey**

I developed and operated programs for three prescription product sales forces, the marketing

Matthew Holley

departments, the grants and sponsorship programs, as well as the company's presentation and publication of research data. My primary duties included reviewing all of the company's promotional materials and providing guidance to the sales team. Key accomplishments included:

- Providing legal representation for a product launch which included disease state awareness communications, data publication and presentation, market research and a variety of commercial activities.
- Writing a guide for Product Managers and vendors on the requirements for prescription product promotional materials.
- Leading the revision of the process, forms and software application for review of promotional materials for prescription, OTC, and other company products.
- Overseeing the cataloging of company trademarks, and preparing and teaching colleagues on registering, renewing and properly using marks.
- Revising the procedures for approval of company participation in medical society events, and events in which the sales team interacts with patients.
- Rewriting sales force guidance, replacing the SOP format and articulating clear instructions on what to do, and not do, in detailing products.
- Working with the Information Technology, Accounts Payable, and other departments to implement revisions to the expense entry system to capture payments to physicians for reporting under the Physician Payments Sunshine Act.
- Overseeing a fair market value assessment and process for approval of programs.

2006 – 2011 **Shionogi Pharma, Inc. (formerly Sciele Pharma, Inc.)** **Atlanta, Georgia**

Senior Director of Compliance

Shionogi is the U.S. subsidiary of an international pharmaceutical company which had a field force of over 700 Sales Representatives in the U.S. as well as multiple co-promotion arrangements, diverse promotional activities and substantial clinical trial programs. I developed, implemented and managed programs to ensure that promotion was consistent with product labeling, that interactions with healthcare providers were ethical and in accordance with applicable restrictions, that data submitted to state and federal programs was accurate, and that clinical trial data was valid and disclosed and published in accordance with federal, European and professional organization standards. My role included preparing SOPs, manuals and other controlled documents setting forth performance standards for procedural tasks and soft skills. Specific programs developed and implemented included:

- Prescription drug sample and voucher distribution and accounting controls
- A Compliance Field Manual and intranet guidance for the sales teams
- Training to prevent off-label promotion and kick-back allegations
- Audit programs for field activities, including product detailing, speaker programs, and advisory boards
- Good documentation practices and document retention procedures
- Learning management system selection and implementation
- Foreign Corrupt Practices Act compliance
- Crisis management preparation

In this role I developed and presented training programs to gatherings of 150+ managers, directors and executives on compliance topics, and I led the development and supervised the operation of training programs for field personnel on a variety of compliance matters. I was a standing member of the company's Promotional Review Board, reviewing all promotional materials, and established and led the Event Review Committee, reviewing all programs that involved interactions with physicians, including speaker programs and advisory boards. I revised the fair market value assessments and process for selecting physicians for participation.

The compliance programs at Shionogi that I developed were clear, effective and comprehensively documented. We received very positive reviews from audits by sanofi-aventis, Novo Nordisk and

Matthew Holley

independent auditors, including The Hudson Group, Deloitte, and Lachman Consultants. Our programs fostered a cooperative culture among our compliance staff and both senior and mid-level managers in the Sales and Marketing Departments. That approach heightened our ability to understand activities across the organization and target programs to address compliance concerns.

2005-2006 **Compliance Implementation Services, LLC** **Media, Pennsylvania**
Program Development Director
At CIS I worked on team that developed and implemented compliance programs for prescription product promotion and government pricing. Particular projects included Medical Science Liaison guidance and training for Shire Pharmaceuticals, and PDMA (product samples) compliance for Stiefel Laboratories. I led projects that assessed entire operations and identified compliance risks based upon the business structure, range of activities and product mix

1994-2004 **Powell, Goldstein, Frazer & Murphy, LLP (now Bryan Cave LLP)** **Atlanta, Georgia**
Attorney at Law
Handled a wide variety of litigation and corporate law matters, with regulatory work in environmental and securities law. Served as primary counsel for numerous clients in technology and information services. Prepared SEC filings for annual and quarterly reports and other filings. Drafted and refined contracts for multitudes of business arrangements in numerous industries, emphasizing client participation in the drafting and clarity in the business terms and operational provisions.

1990-1991 **Pine Forest High School** **Pensacola, Florida**
Teacher
Taught psychology and sociology for juniors and seniors, as well as created courses for Graduate Equivalent Diploma programs. Customized and taught interactive courses with substantial community involvement and student participation with brain injury, blindness coping, and brain science programs.

1986-1990 **Captain, U.S. Air Force** **Biloxi, Mississippi**
Lead a consulting unit in the Air Training Command, restructuring training programs for electronics, health care, air combat control operations, and computer programming. Analyzed career structures, recommended merging and adding career fields and associated ASVAB requirements, training program content and career escalation criteria.

Presentations

- Presenter, Promotional Review Committee Compliance and Best Practices
  Morristown, New Jersey October, 2015
  Topic: Lawsuit risk from prescription product promotion

- Panelist, Focus on Pharma Intellectual Property Conference
  Washington, DC September, 2015
  Topic: Creating, Protecting and Enforcing High Value IP Assets

- Panelist, Global IP Conference and Exhibition
  New York, June 2014
  Topic: Negotiating, Enacting and Managing Outsoureing Relationships

- Presenter, PDMA Alliance Annual Meeting
  San Diego, California October, 2010
  Topic: Simplifying Prescription Sample Program Guidance

- Presenter, Commercial Compliance for Pharmaceutical and Medical Device Companies
  Washington, D.C., April 2010
  Topic: Alternate Formats for Writing Field Sales Team Guidance

Matthew Holley

Education

J.D. Indiana University School of Law, 1995
M.S. University of Southern Mississippi, 1989
B.S. Indiana University, 1986

Community Service

- Animal Use and Institutional Review Board
  U.S. Air Force Keesler Medical Center, Biloxi, Mississippi 1987-1990

- Chair, Institutional Review Board
  AIDS Research Consortium of Atlanta 2003-2009

Boards and Consultancies

Global Safety Management, Inc. Tampa, Florida
Board of Directors and Compensation Committee Member Jan 2016 – Oct 2016

Thanks Again, LLC Atlanta, Georgia
Legal and business advisor 2007 - Present

Bar Admissions

Georgia
New Jersey (as in-house counsel)

Maria Herrera

From: Lam, Maggie P. <lam@porziols.com>
Sent: Tuesday, May 11, 2021 10:49 AM
To: Maria Herrera
Subject: RE: Pharming Healthcare, Inc. - Pending Wholesaler application

Follow Up Flag: Follow up
Flag Status: Completed

Maria,

Yes, I confirmed with the company that he has the required experience.

Regards,

Maggie

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, May 11, 2021 12:30 PM
To: Lam, Maggie P. <lam@porziols.com>
Subject: RE: Pharming Healthcare, Inc. - Pending Wholesaler application

EXTERNAL MESSAGE

Good Morning Maggie,

In finalizing the application for Pharming Healthcare, Inc. we came upon the facility manager's resume and we weren't sure of his qualifications, please verify that he meets the hour qualifications based on NAC 639.5005 (2)(a).

(a) Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
775-850-1440
m.herrera@pharmacy.nv.gov

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☒ Publicly Traded Corporation – Pages 1,2,3,4
☐ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Tetraphase Pharmaceuticals, Inc.

Physical Address: 201 Jones Road Suite 400

City: Waltham State: MA Zip Code: 02451

Telephone Number: 617-715-3600 Fax Number: _____

Toll Free Number: _____

E-mail: compliance@ljpc.com Website: www.tphase.com

Facility Manager: Larry Edwards

Professional qualifications and experience of facility manager: See attached resume

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers
☒ Other: Specialty Distributors

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

Received 6/9/14

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A
Address:

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Larry Edwards
Print Name of Authorized Person

03/23/2021
Date

Board Use Only	Date Processed: 6/18/2021	Amount: $500 Check # 3543413

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: DE

Parent Company if any: La Jolla Pharmaceutical Company

Corporation Name: Tetraphase Pharmaceuticals, Inc.

Mailing Address: 201 Jones Road Suite 400

City: Waltham State: MA Zip: 02451

Telephone: 617-715-3600 Fax: _____

Contact Person: Larry Edwards

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: 07/07/2006

Registration number issued: 4186628

Stock Exchange: LJPC

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM
239 CAUSEWAY ST., SUITE 500, BOSTON, MA 02114

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000769	01/26/2021	01/26/2022	Virtual Drug Manufacturers

ISSUED TO

TETRAPHASE PHARMACEUTICALS, INC.
201 JONES ROAD
SUITE 400
WALTHAM, MA 002451
ATTN: LARRY EDWARDS PRESIDENT AND CEO

COMMISSIONER OF PUBLIC HEALTH

RECIPIENT'S COPY

NEW

841581

CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

NUMBER	ISSUED	EXPIRES	TYPE
MA0000769	01/26/2021	01/26/2022	Virtual Drug Manufacturers

ISSUED TO

TETRAPHASE PHARMACEUTICALS, INC.
201 JONES ROAD
SUITE 400
WALTHAM, MA 002451
ATTN: LARRY EDWARDS PRESIDENT AND CEO

NEW

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
Drug Control Program
239 Causeway Street, Suite 500
Boston, MA 02114

Tel: 617-973-0949
TTY : 617-973-0988
www.mass.gov/dph/boards

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

May 18, 2021

RE: Verification of Massachusetts Controlled Substances Registration (MCSR)

To Whom It May Concern:

Please be advised that **TETRAPHASE PHARMACEUTICALS, INC. (MA0000769)**, located at **201 JONES ROAD, SUITE 400, WALTHAM MA, 02451** has an active MCSR as a Virtual Drug Manufacturer and is in good standing. The current registration has an issue date of **01/26/2021** and expires on **01/26/2022** This Facility was last Reviewed by the Drug Control Program on **01/26/2021** and has met all the requirements for the Virtual Drug Manufacturer Controlled Substances Registration.
As of the date on this letter, there has been no disciplinary action issued by the Drug Control Program for this registrant.

Should you have any questions or concerns regarding the above information, please contact us at 617-973-0949.

Traci Westgate
Director, MCSR

Online Licensure Verification Services: https://www.mass.gov/service-details/registration-verification-for-mcsr . The Information provided in this 'Certified Statement' is based on the records maintained by the Massachusetts Bureau of Health Professions Licensure and its licensing boards. Facilities are deemed to be in good standing if their license is current and not subject to any disciplinary status on the date of issuance of the 'Certified Statement'. Disciplinary status is defined as voluntary surrender, revocation, suspension, or probation of a license.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TETRAPHASE PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF FEBRUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4186628 8300

SR# 20210552116

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202558007

Date: 02-22-21

TETRAPHASE PHARMACEUTICALS

Description of Operations

Tetraphase Pharmaceuticals, Inc. ("Tetraphase") is a virtual manufacturer of prescription drugs located in Watertown, MA. Tetraphase is a publicly traded company on the NASDAQ stock exchange under the symbol TTPH. Tetraphase Pharmaceuticals, Inc. operates as a clinical-stage life science company with a synthetic chemistry technology platform that has the potential to address the global health crisis caused by antibiotic resistance. Tetraphase's product is manufactured by a contract manufacturer and will be distributed to customers by a third-party logistics provider (3PL).

Tetraphase Pharmaceuticals, Inc. uses the following contract manufacturer to produce the product:

Patheon
5900 Martin Luther King Jr. Hwy
Greenville, NC 27834
FDA: 1018495

Products:
Patheon manufactures and packages Tetraphase's product. At no time does Patheon own the product, contract with Tetraphase's customers, invoice, nor sell a Tetraphase product. Tetraphase's products are not controlled substances. Accordingly, Tetraphase is not required to maintain DEA registration.

Labeler Code: 71773

Third-Party Logistics Information:

For distribution into the commercial supply channels, **Cardinal Health "SPS"** acts as Tetraphase's third-party logistics (3PL) provider to manage the storage and distribution of Tetraphase's product to customers throughout the United States. **Cardinal Heath "SPS"** address is:

Cardinal Health "SPS"
15 Ingram Boulevard
LaVergne, TN 37086

Tetraphase's hours of operation are 8:30 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday.

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

Current through May 14, 2021

You have searched Finished drug products

Search Results: *'tetraphase'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product T Name
Xerava	71773-050-05	50 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA211109	Tetraphase Pharmaceuticals, Inc.	71773-050	eravacycline	ERAVACYCLINE DIHYDROCHLORIDE	HUMAN PRESCRIP DRUG
Xerava	71773-050-12	50 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA211109	Tetraphase Pharmaceuticals, Inc.	71773-050	eravacycline	ERAVACYCLINE DIHYDROCHLORIDE	HUMAN PRESCRIP DRUG
Xerava	71773-100-12	100 mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	NDA211109	Tetraphase Pharmaceuticals, Inc.	71773-100	eravacycline	ERAVACYCLINE DIHYDROCHLORIDE	HUMAN PRESCRIP DRUG

Showing 1 to 3 of 3 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

Verified
M.H 6/11/2021

TETRAPHASE PHARMACEUTICALS

Ownership

Tetraphase Pharmaceuticals is a virtual manufacturer of pharmaceuticals that is publicly traded on the NASDAQ stock exchange (TTPH). Tetraphase Pharmaceuticals, Inc. is incorporated in the state of Delaware.

Company Information

Tetraphase Pharmaceuticals, Inc.
201 Jones Road Suite 400
Waltham, MA 02451
(617) 715-3600
Tax ID: 205276217

Corporate Officers

Larry Edwards, Chief Executive Officer

Michael Hearne, Chief Financial Officer

Larry Edwards has been employed with Tetraphase, since 2015. Tetraphase is a virtual manufacturer who utilizes a Contract Manufacturer to manufacture product and a 3PL to store and distribute product. Larry Edwards is familiar and actively involved with the responsibilities associated with the distribution of pharmaceutical drug packages including shipping, inventory, order count, recordkeeping, and storage through Tetraphase's Third Party Logistics Provider. Larry Edwards is also aware of the USP temperature guidelines and quality control utilized by Tetraphase's Contract Manufacturer. In addition, Larry Edwards is familiar with the company's procedures on drug recall and the process for customer returns and handling.

Larry Edwards

[redacted] Whispering Way, Stow, MA 01775 ♦ [redacted]

EXECUTIVE PROFILE

Dynamic **Commercial Leader** with 24 years of impactful and progressive pharmaceutical and biotech experience. Broad expertise and global enterprise-wide perspective established through executive and management roles exposed to diverse commercial disciplines with consistent success. Deep commercial launch experience acquired from several global and domestic product launches in the anti-infective therapeutic areas. Outstanding presentation, communication and cross-functional team management and team building skills. High-energy, results-oriented leader with an entrepreneurial and a "roll-up my sleeves" attitude.

PROFESSIONAL EXPERIENCE

Tetraphase Pharmaceuticals, 6/2015 - Present

President & CEO — ***Present***

- President & CEO of Tetraphase Pharmaceuticals

Chief Operating Officer — ***3/2017-7/2019***

- Work with CEO on all Investor related activities and Financing opportunities
  - Successfully closed a $70MM equity round in 3Q 2017
- Responsible for building and providing leadership to the US and EU Commercial Organization
  - Currently building and managing a Global Distribution Strategy and Infrastructure
    - Build, hire and lead Global supply chain team
  - Develop an innovative global strategy for Marketing and Sales to ensure a successful launch
    - Hire and lead Marketing, Sales, and Training teams
    - Hire and lead Sales Operations Team and analysts
- Continue to lead all Global pre-launch Marketing activities and Pricing/Reimbursement
- Lead all Business Development activities
  - Focus efforts on Partnering opportunities outside of the US and EU 5
    - Currently closing two definitive agreements with ex-US partners
    - Finalizing definitive agreement for back-up manufacturer
  - Potential in-licensing opportunities US and EU 5
- Work with Clinical team on new study designs and lifecycle management plans for late and early stage assets
- Lead for pipeline valuation and prioritization efforts
- Lead Medical Affairs and provide input into market development activities
  - Lead efforts in building Scientific Platform, Lexicon, Scientific Response Letters
  - Hire and oversee management of medical affairs group
- Provide Quarterly updates and input to Board of Directors on all Commercial Strategies and Plans
- Work with Executive team to provide quarterly earnings updates to the Street and Investors

Chief Commercial Officer — ***6/2015-2/2017***

- Promoted from Vice President of Commerical Operations to Chief Commecial Officer in 2016
- Responsible for all pre-launch Marketing Activities (Domestic and Global)
  - Brand Naming, Brand Hallmarks, and Brand Creative Development
  - Develop Brand Positioning, Messaging, Value Proposition and Lead all Market Research
  - Forecasting work for eravacycline and early stage compounds
  - Pricing and Market Access Strategy
  - Hospital Segmentation work and Sales Force Structure
  - Market Development plans for late and early stage compounds
- Hire and oversee Marketing team (HCP, Scientific Lead and Forecasting)
- Commercial point for all labeling Discussions (FDA and EMA)

- Assist with Business Development activities in US and ROW

Cubist Pharmaceuticals, 4/2014 – 6/2015

Executive Director of Marketing, Gram Negative Franchise ***4/2014 – 6/2015***

- Managed a team of Marketers who were responsible for all facets of marketing - HCP promotions (personal and non-personal), Field Sales point, Physician Medical Education, Congresses, Market Research and Forecasting
- Responsible for all pre-launch and post launch Marketing activities for new gram-negative compound ZERBAXA
- Commercial Lead for all label discussions with the FDA
- Lead for Lifecycle management work for antibacterial franchises
- Managed a budget of $13MM dollars and ended the year at 100% to plan.
- Worked with Sales Planning and Sales Management on;
    - Guidance and input around Incentive Compensation for field sales force
    - Developed methodology around Hospital and Physician targets
    - Training initiatives and sales force execution
- Commercial point for Cubist/Merck integration

Merck & Co., Inc., 1999 – 4/2014

Global Marketing Director, Clostridium Difficile & New Infectious Disease Products ***2010-4/2014***

- Responsible for all pre-launch Marketing activities for early and late stage Hospital ID products
    - Provide commercial strategy and direction to Basic and Clinical Research for product/program development
    - Development of Global Scientific Platforms for multiple new products
    - Commercial point for all labeling initiatives
    - Development of Value/Payer Proposition and Global Brand Positioning
    - Led activities with Countries to ensure the appropriate Health Economic plans were in place
        - Key endpoints in clinical studies and Pricing and reimbursement
    - Lead for all Market Research projects - buying process, benefit ladder, customer portraits, and drivers/barriers
    - Management of Thought Leader Development for all compounds (Ad Boards, Expert Input Forums)
    - Development of Lifecycle Management plan
- Worked on an acquisition that will potentially bring cumulative sales > $11B over lifecycle of the compound
- Spearheaded development timeline change for MK-7655 which allows it to come to market 1.5 years earlier ($61MM)

Associate Director of Marketing, Vaccines and Infectious Diseases ***2007-2010***

- Franchise lead for Integration planning for Legacy Merck and Legacy Schering Plough AB/AF products
- Developed Scientific, and Promotional Strategy for successful launch of New Pediatric Indication, which led to strategic account wins estimated around $39mm dollars, and maintained market leadership throughout 2008-2009
- Led multiple Market Research projects that led to succinct messaging, improved strategy, and updated buying process
- Developed messaging platform for CANCIDAS, resulting in an additional $25mm dollars by gaining share from Fluconazole
- I worked with multiple Agencies while managing a $5.8mm, $4.9mm, and $3.7mm promotional budget respectively, appropriately funding across the marketing mix to drive over $318mm ('07'), over $279mm ('08'), and over $205mm ('09') in gross sales revenue
- Developed targeting tool for the field that helped them pull through Marketing Strategy
- Indirectly managed 3 separate departments that consisted of 4 FTE's
- Led all Scientific Strategy Initiative for the US Antifungal Franchise
- Franchise Point for all labeling initiatives, Investigator Initiated Study Programs and Academic Collaborative Studies

Western Region Sales Director **2005-2007**

- Consistently grew district revenue, and exceeded plan for 2 consecutive years in a market that was declining at a rate of 3%
- Managed a diverse team of 10 sales representatives covering 9 States with a total district revenue of $30mm in 2005, $37mm in 2006, and $51mm in 2007
- Coached and trained representatives, ensuring that the marketing strategy was effectively executed at local territory level and ensured the pull through of Regional tactical plans
- Designed 2007 National Sales Incentive Plan for Managers and Representatives
- Helped mentor two new managers and assisted them with business reviews and account planning
- Consistently received above average 360 review feedback from my team, colleagues and stakeholders

Brand Trainer (Hospital/ID/Oncology/Specialty) **2003-2005**

- Developed innovative training programs; Day in the Life of an Ophthalmologist, Tumor Boards, Hospitalist Training and Web based training while collaborating with National Thought Leaders
- Developed accelerated curriculum for the Oncology team increasing their knowledge of the Oncology marketplace
- Collaborated with Marketing and other cross functional teams to ensure training was consistent with franchises strategic plans
- Led training initiatives for Managers, Managed Care, and 2 product launch meetings
- Received numerous Awards for Excellence, and Special Achievement Awards

Hospital Acute Care Representative, Phoenix AZ **2001-2003**

- Managed two territories in '02; growing primary territory to 118% to plan, and grew new territory from 49% to plan to 101%
- Ranked second in the Nation for INVANZ sales in '02'; Received several outstanding selling awards throughout '02'
- Finished at 142% to plan for total product portfolio in '01'
- Accountable for the largest PRIMAXIN and CANCIDAS sales objectives in the District
- Successfully launched 2 new products; CANCIDAS and INVANZ

Office Based Representative, Phoenix AZ **1999-2001**

- Number one cluster in the South Central for '99' and '00' at 112% and 129% to plan
- Won Rookie of the Year in '99'
- Covered vacant A&A Specialty Representative position for 7 months while continuing to promote other products

AT&T Communications, 1996-1999

Major Account Manager, Phoenix AZ **1998-1999**

- Top Producer and Presidents Club award winner '98'
- Conducted extensive business analysis work to assist representatives with acquiring new accounts, and achieving monthly quotas
- Assisted account executives in career and business development, worked closely with Human Resources to achieve set goals
- Responsible for all facets of operational management; local marketing, hiring, training, coaching, expense management

Commercial Account Executive, Phoenix AZ **1996-1997**

- Top Producer in ' 97'
- Masters club award winner
- In '97' achieved 250% to plan monthly average
- Sold the first multimillion dollar 1.9GHz Wireless Office System for all of AT&T
- In '96' achieved 125% to plan for a monthly average, after first six months of market development

▼ EDUCATION:

Masters of Business Administration

- St. Joseph's University, Philadelphia PA

Bachelors of Science in Business & Healthcare Administration

- Ohio University, Athens OH

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 1-36282

LA JOLLA PHARMACEUTICAL COMPANY

(Exact name of Registrant as specified in its Charter)

California	33-0361285
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Jones Road, Suite 400 Waltham, MA	02451
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 715-3600

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	LJPC	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Capital Market on June 30, 2020, was $78.0 million.

As of February 8, 2021, there were 27,428,407 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Shareholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

		Page
FORWARD-LOOKING STATEMENTS		1
PART I		
Item 1.	Business	2
Item 1A.	Risk Factors	25
Item 1B.	Unresolved Staff Comments	37
Item 2.	Properties	37
Item 3.	Legal Proceedings	37
Item 4.	Mine Safety Disclosures	37
PART II		
Item 5.	Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities	38
Item 6.	Selected Financial Data	38
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	39
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	48
Item 8.	Financial Statements and Supplementary Data	49
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	49
Item 9A.	Controls and Procedures	49
Item 9B.	Other Information	49
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	50
Item 11.	Executive Compensation	50
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters	50
Item 13.	Certain Relationships and Related Transactions, and Director Independence	50
Item 14.	Principal Accountant Fees and Services	50
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	51
Item 16	Form 10-K Summary	53
	SIGNATURES	54

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements can be identified by words such as "intends," "believes," "anticipates," "indicates," "plans," "expects," "suggests," "may," "should," "potential," "designed to," "will" and similar expressions that predict or indicate future events and trends that do not relate to historical matters. You should not unduly rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control. These risks, uncertainties and other factors may cause our actual results, performance or achievements to be materially different from the anticipated future results, performance or achievements expressed or implied by the forward-looking statements.

These forward-looking statements include, but are not limited to, statements regarding:

- our ability to grow net sales of GIAPREZA™ (angiotensin II) and XERAVA™ (eravacycline);
- our ability to maintain an effective sales and marketing organization;
- the potential market size for GIAPREZA and XERAVA;
- our ability to obtain an uninterrupted supply of GIAPREZA and XERAVA from our contract manufacturers;
- GIAPREZA's and XERAVA's market exclusivity period as a result of the enforcement of regulatory exclusivity and the validity and enforceability of issued and pending patents covering GIAPREZA and XERAVA;
- our ability to comply with our obligations under our license agreements;
- our ability to realize the benefits from the acquisition of Tetraphase Pharmaceuticals, Inc.;
- our ability to hire and retain key employees;
- our overall financial performance, including but not limited to net product sales and net cash used for or provided by operating activities, including any milestone and/or royalty payments resulting from licensing agreements and any distributions received in connection with our non-voting profits interest;
- our capital requirements and our potential need for, and ability to obtain, additional financing; and
- our ability to maintain effective internal controls.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from the anticipated future results, performance or achievements expressed or implied by any forward-looking statements, including the factors described under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." You should evaluate all forward-looking statements made in this Annual Report on Form 10-K, including the documents we incorporate by reference, in the context of these risks, uncertainties and other factors.

We caution you that the risks, uncertainties and other factors referred to above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will affect us or our business in the way expected. All forward-looking statements in this Annual Report on Form 10-K apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances.

PART I

In this Annual Report on Form 10-K, all references to "we," "our," "us," "La Jolla" or "the Company" refer to La Jolla Pharmaceutical Company, a California corporation, and our wholly owned subsidiaries, including La Jolla Pharma, LLC and Tetraphase Pharmaceuticals, Inc., on a consolidated basis.

Item 1. Business

Overview

We are dedicated to the development and commercialization of innovative therapies that improve outcomes in patients suffering from life-threatening diseases. GIAPREZA™ (angiotensin II) injection is approved by the U.S. Food and Drug Administration ("FDA") as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. XERAVA™ (eravacycline) for injection is approved by the FDA as a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections ("cIAI") in patients 18 years of age and older.

On July 28, 2020, La Jolla completed its acquisition of Tetraphase Pharmaceuticals, Inc. ("Tetraphase"), a biopharmaceutical company focused on commercializing XERAVA, for $43 million in upfront cash plus potential future cash payments of up to $16 million. Financial results for the period ending December 31, 2020 include Tetraphase's financial results subsequent to the acquisition closing date of July 28, 2020.

On January 12, 2021, La Jolla Pharmaceutical Company and certain of its wholly owned subsidiaries, including La Jolla Pharma, LLC and Tetraphase, entered into an exclusive licensing agreement (the "PAION License") with PAION AG and its wholly owned subsidiary (collectively, "PAION") to commercialize GIAPREZA and XERAVA in the European Economic Area, the United Kingdom and Switzerland whereby La Jolla is entitled to receive an upfront cash payment of $22.5 million plus potential commercial milestone payments of up to $109.5 million and double-digit tiered royalty payments.

As of December 31, 2020, La Jolla had $21.2 million of cash and cash equivalents. On a pro forma basis, adjusting for $18.9 million of upfront net proceeds from the PAION License, net of the amounts due under the George Washington University and Harvard University license agreements, La Jolla had cash and cash equivalents of $40.1 million.

For the three and twelve months ended December 31, 2020, GIAPREZA U.S. net sales were $8.7 million and $29.3 million, respectively, up 19% and 27%, respectively, from the same periods in 2019. Subsequent to July 28, 2020 and through December 31, 2020, XERAVA U.S. net sales were $4.2 million. For the three and twelve months ended December 31, 2020, including the period prior to the acquisition of Tetraphase, XERAVA U.S. net sales were $2.3 million and $8.2 million, respectively, up 53% and 128%, respectively, from the same periods in 2019.

Product Portfolio

Product	Indication	Pivotal Studies	Regulatory Status
GIAPREZA™ (angiotensin II)	Septic or other distributive shock[1]	321-patient, multinational, double-blind, randomized, placebo-controlled study	FDA-approved Dec 2017 European Commission-approved Aug 2019
XERAVA™ (eravacycline)	Complicated intra-abdominal infections[2]	538-patient, multinational, double-blind, randomized, active-controlled study 499-patient, multinational, double-blind, randomized, active-controlled study	FDA-approved Aug 2018 European Commission-approved Sep 2018

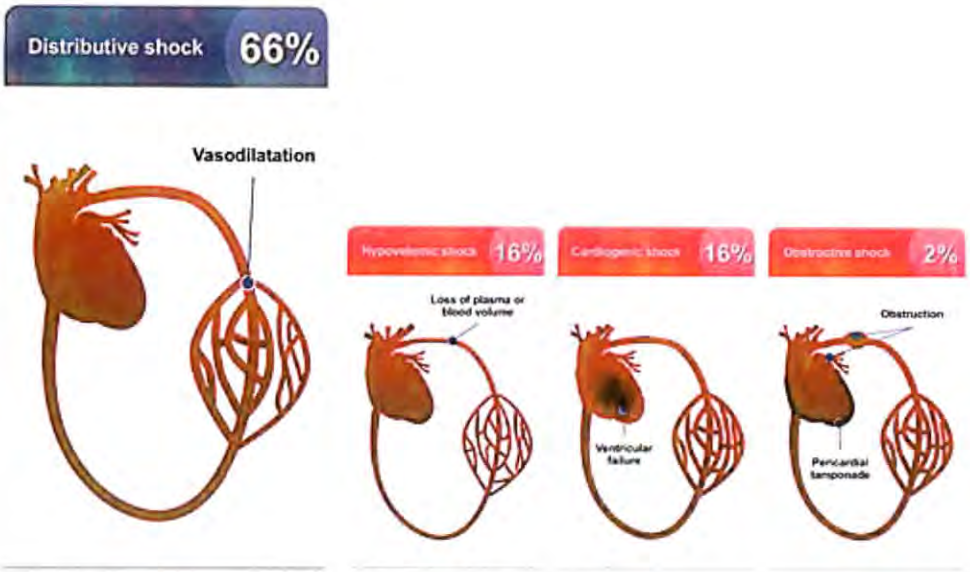
(1) U.S.: GIAPREZA is a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock
European Union: GIAPREZA is indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies
(2) U.S.: XERAVA is a tetracycline class antibacterial indicated for the treatment of cIAIs in patients 18 years of age and older
European Union: XERAVA is indicated for the treatment of cIAI in adults

GIAPREZA™ (angiotensin II)

GIAPREZA™ (angiotensin II) injection is approved by the FDA as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. GIAPREZA is approved by the European Commission ("EC") for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. GIAPREZA mimics the body's endogenous angiotensin II peptide, which is central to the renin-angiotensin-aldosterone system ("RAAS"), which in turn regulates blood pressure. GIAPREZA is marketed in the U.S. by La Jolla Pharmaceutical Company on behalf of La Jolla Pharma, LLC, its wholly owned subsidiary, and will be marketed in Europe by PAION AG on behalf of La Jolla Pharma, LLC.

Distributive shock is the most common form of shock (Vincent et al, *New England Journal of Medicine* 2013; 369(18):1726−1734).

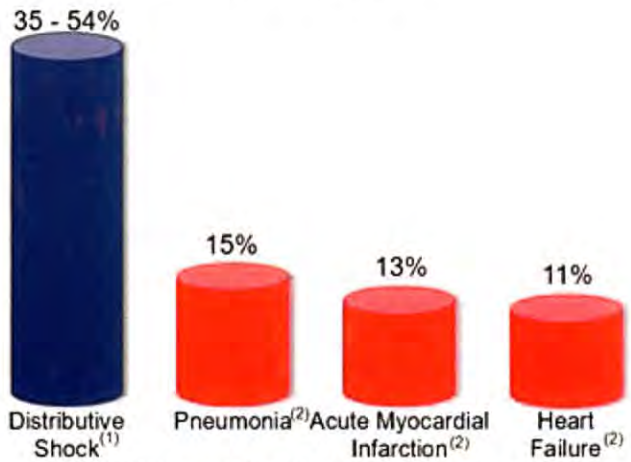
Types of Shock(1)



(1) Vincent et al, *New England Journal of Medicine* 2013; 369(18):1726−1734

Distributive shock is a leading cause of death in hospitalized patients. Septic shock accounts for more than 90% of distributive shock (Vincent et al, *New England Journal of Medicine* 2013; 369(18):1726–1734). Shock affects one-third of patients in the intensive care unit ("ICU") (Sakr et al, *Critical Care Medicine* 2006; 34:589–597). The mortality rate of distributive shock exceeds that of most acute conditions requiring hospitalization.

Mortality Rate

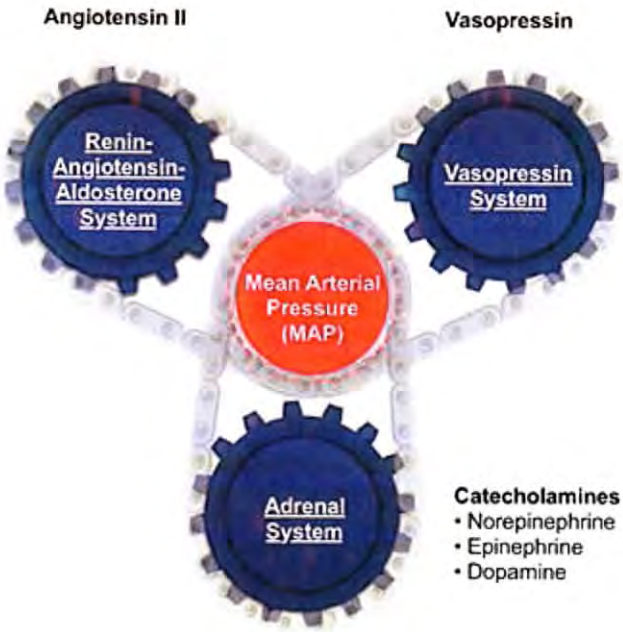


(1) Based on the 28-day mortality rates of: (i) 35% from the vasopressin arm of Russell et al, *New England Journal of Medicine* 2008; 358:877–87; (ii) 49% from the norepinephrine arm of De Backer et al, *New England Journal of Medicine* 2010; 362:779–89; and (iii) 54% from the placebo arm (high-dose norepinephrine or equivalent) of Khanna et al, *New England Journal of Medicine* 2017; 377:419–430

(2) 30-day mortality rate from Medicare.gov

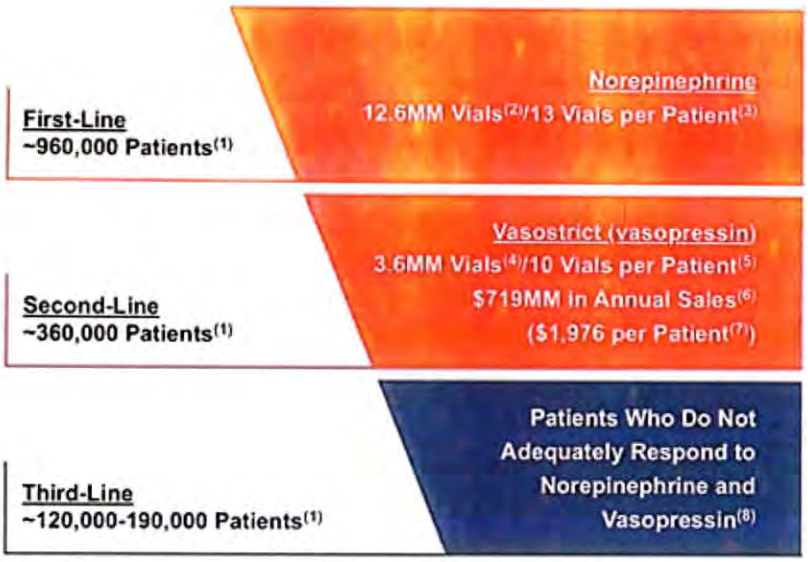
The RAAS is one of three systems that work in harmony to regulate blood pressure. GIAPREZA regulates blood pressure through the RAAS. Other therapeutic options regulate blood pressure through the adrenal system and vasopressin system.

In Healthy Individuals, Three Systems Work in Harmony to Regulate Blood Pressure



Annually in the U.S., approximately 130,000–200,000 patients fail to respond to current vasopressor options.

Response to Current Vasopressor Options

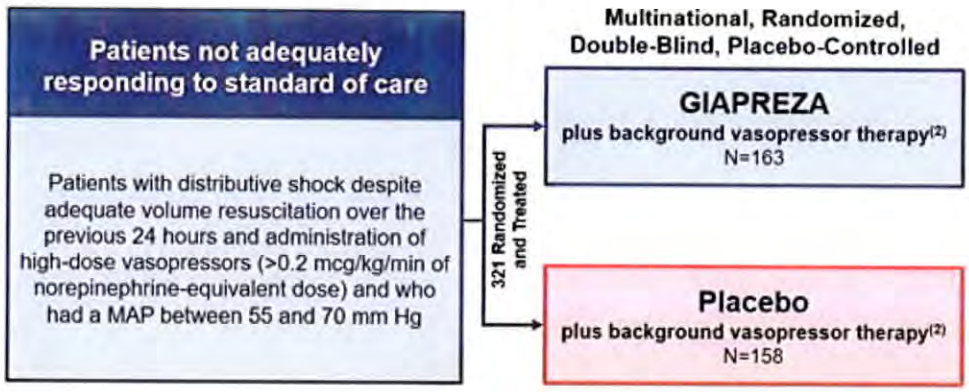


(1) Annually in the U.S.
(2) Year ended December 31, 2020 per Symphony Health Solutions
(3) Estimate based on Russell et al, *New England Journal of Medicine 2008*; 358:877–87 and Asfar et al, *New England Journal of Medicine 2014;* 370:1583–93
(4) Annual sales per Endo International plc SEC filings, divided by price per vial per Wolters Kluwer *PriceRx*
(5) Estimate based on Dunser et al, *Circulation* 2003; 107:2313–2319 and Gordon et al, *Critical Care Medicine* 2014; 42(6):1325–1333
(6) Year ended December 31, 2020 per Endo International plc SEC filings
(7) $212.38 per vial per Wolters Kluwer PriceRx, multiplied by 10 vials per patient
(8) Estimate based on: 35.4% 28-day mortality rate in vasopressin arm of Russell et al, *New England Journal of Medicine* 2008; 358:877–87; 48.5% 28-day mortality rate in norepinephrine arm of De Backer et al, *New England Journal of Medicine* 2010; 362:779–789; and 54.6% non-responder rate on vasopressin from Sacha et al, *Annals of Intensive Care* 2018; 8:35

Angiotensin II for the Treatment of High-Output Shock ("ATHOS-3")

GIAPREZA was approved by the FDA and the EC based on the results of ATHOS-3, which were published in the *New England Journal of Medicine* in August 2017. ATHOS-3 was a multinational, randomized, double-blind, placebo-controlled study in which 321 adults with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy received either GIAPREZA or placebo, both in addition to background vasopressor therapy. The primary endpoint was mean arterial pressure ("MAP") response, defined as a MAP of 75 mm Hg or higher or an increase in MAP from baseline of at least 10 mm Hg without an increase in the dose of background vasopressors at Hour 3 (Khanna et al, *New England Journal of Medicine* 2017; 377:419–430).

ATHOS-3 Study Design(1)

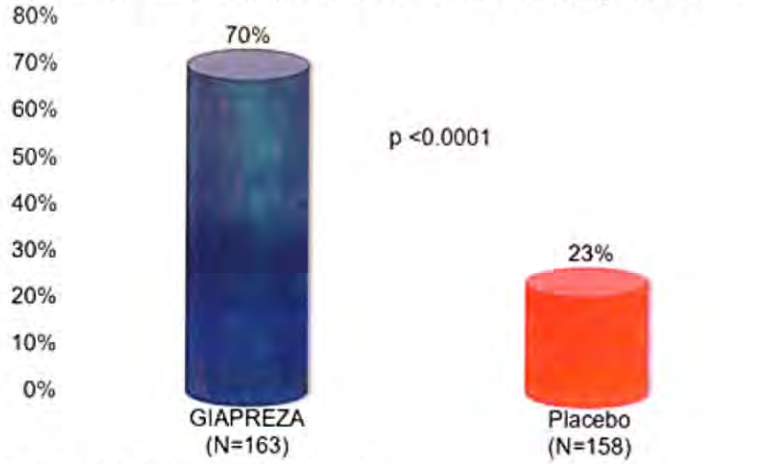


Primary Endpoint: MAP response of ≥75 mm Hg or an increase from baseline of ≥10 mm Hg at Hour 3, without an increase in the dose of background vasopressors

MAP=mean arterial pressure
(1) Khanna et al, *New England Journal of Medicine* 2017; 377:419–430
(2) Standard-of-care vasopressors included norepinephrine, epinephrine, dopamine and vasopressin

GIAPREZA significantly improved blood pressure response. Specifically, the primary endpoint was achieved by 70% of GIAPREZA-treated patients compared to 23% of placebo-treated patients (p <0.0001).

Primary Endpoint: Mean Arterial Pressure Response(1),(2)

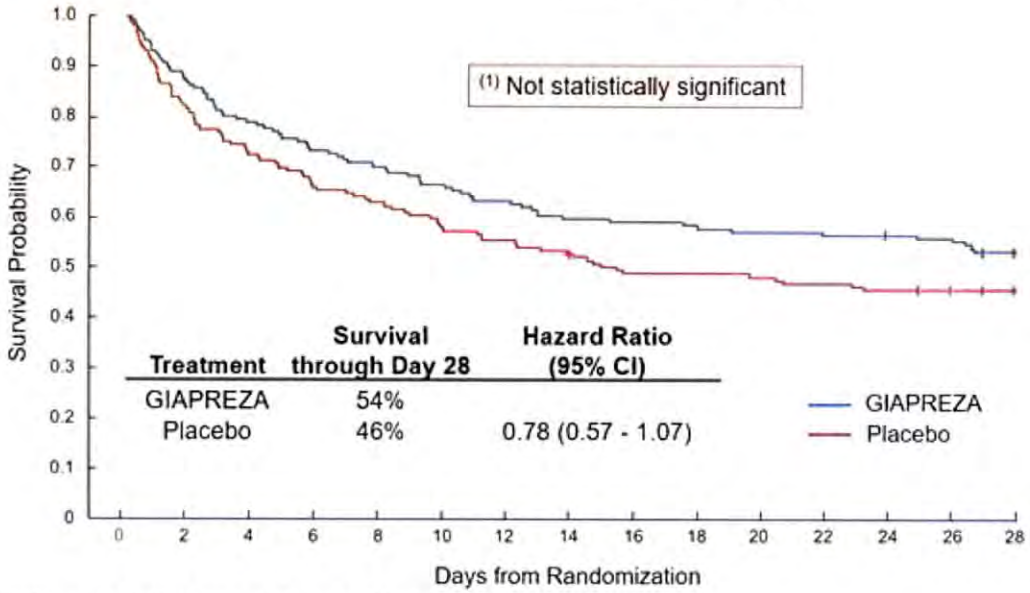


(1) GIAPREZA FDA prescribing information
(2) MAP response of 75 mm Hg or higher or an increase from baseline of at least 10 mm Hg at Hour 3 without an increase in the dose of background vasopressors

GIAPREZA provides the ability to rapidly achieve and adjust therapeutic response. GIAPREZA rapidly increased MAP with a median time to MAP response of approximately 5 minutes. The plasma half-life of GIAPREZA is less than 1 minute.

In addition, a positive survival trend was observed. Mortality through Day 28 was 46% on GIAPREZA and 54% on placebo (hazard ratio 0.78; 95% confidence interval 0.57–1.07).

Positive Survival Trend Observed (N=321)(1),(2)



(2) Khanna et al, *New England Journal of Medicine* 2017; 377:419–430

The most common adverse reactions that were reported in greater than 10% of GIAPREZA-treated patients were thromboembolic events.

Adverse Reactions Occurring in ≥4% of Patients Treated with GIAPREZA and ≥1.5% More Often than in Placebo-treated Patients(1)

	GIAPREZA (N=163)	Placebo (N=158)
Thromboembolic events(2)	21 (12.9%)	8 (5.1%)
Deep vein thrombosis	7 (4.3%)	0 (0.0%)
Thrombocytopenia	16 (9.8%)	11 (7.0%)
Tachycardia	14 (8.6%)	9 (5.7%)
Fungal infection	10 (6.1%)	2 (1.3%)
Delirium	9 (5.5%)	1 (0.6%)
Acidosis	9 (5.5%)	1 (0.6%)
Hyperglycemia	7 (4.3%)	4 (2.5%)
Peripheral ischemia	7 (4.3%)	4 (2.5%)

(1) GIAPREZA FDA prescribing information
(2) Including arterial and venous thrombotic events

Note: There is a potential for venous and arterial thrombotic and thromboembolic events in patients who receive GIAPREZA. As stated in the GIAPREZA FDA prescribing information, use concurrent venous thromboembolism ("VTE") prophylaxis.

Percentage of Patients Experiencing ≥1 Adverse Event, ≥1 Serious Adverse Event and Discontinuing Treatment Due to an Adverse Event(1)

	GIAPREZA (N=163)	Placebo (N=158)
Percentage of patients experiencing ≥1 adverse event	87%	92%
Percentage of patients experiencing ≥1 serious adverse event	61%	67%
Percentage of patients discontinuing treatment due to an adverse event	14%	22%

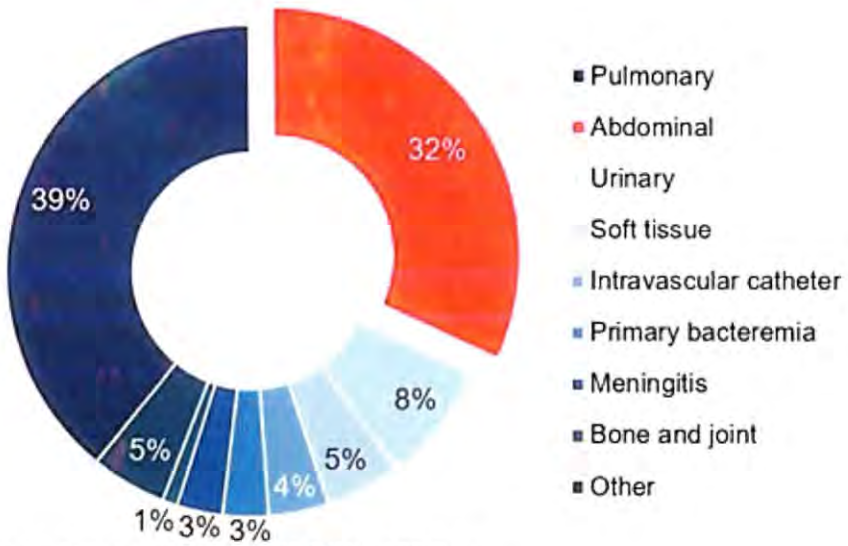
(1) Khanna et al, *New England Journal of Medicine* 2017; 377:419–430

XERAVA™ (eravacycline)

XERAVA™ (eravacycline) for injection is approved by the FDA as a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections ("cIAI") in patients 18 years of age and older. XERAVA is approved by the EC for the treatment of cIAI in adults. XERAVA is marketed in the U.S. by Tetraphase Pharmaceuticals, Inc., a wholly owned subsidiary of La Jolla, and will be marketed in Europe by PAION AG on behalf of Tetraphase Pharmaceuticals, Inc.

cIAIs are the second most common source of severe sepsis in the ICU (Brun-Buisson et al, *JAMA* 1995; 274(12):968–974). cIAIs are defined as consequences of perforations of the gastrointestinal tract that result in contamination of the peritoneal space (Solomkin et al, *Clinical Infectious Diseases* 2018; 69(6):921–929).

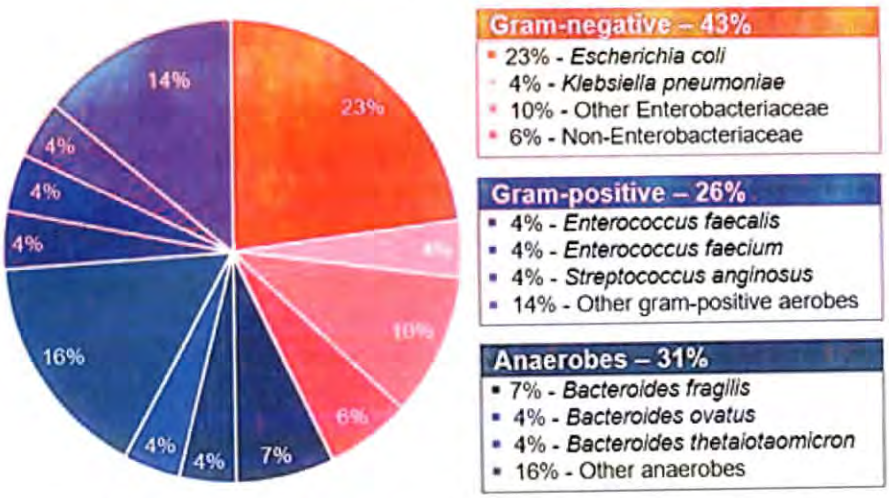
Source of Severe Sepsis in the ICU (%)(1)



(1) Brun-Buisson et al, *JAMA* 1995; 274(12):968–974

The use of antimicrobial agents that have activity against gram-negative, gram-positive and anaerobic pathogens is strongly recommended for the empiric treatment (treatment without a specific pathogen diagnosis) of patients with cIAI. The increased prevalence of resistant bacteria makes the selection of appropriate treatment more challenging (Mazuski et al, *Surgical Infections* 2017; 18(1):1–76).

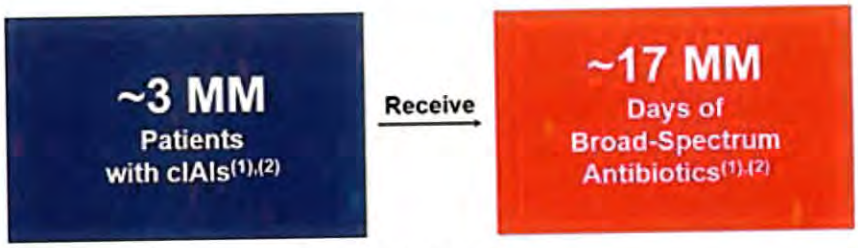
2,733 Baseline Pathogens in 846 Patients with cIAI
3.2 Pathogens/Patient(1)



(1) Data on file from IGNITE1 and IGNITE4 microbiologic intent-to-treat (micro-ITT) population

Approximately 3 million patients with cIAIs receive approximately 17 million days of broad-spectrum antibiotics.

~3 MM Patients with cIAIs Receive Broad-Spectrum Antibiotics



(1) 2014 Decision Resources AMR Hospital Database
(2) Annually in the U.S. and EU5 (France, Germany, Italy, Spain and the United Kingdom)

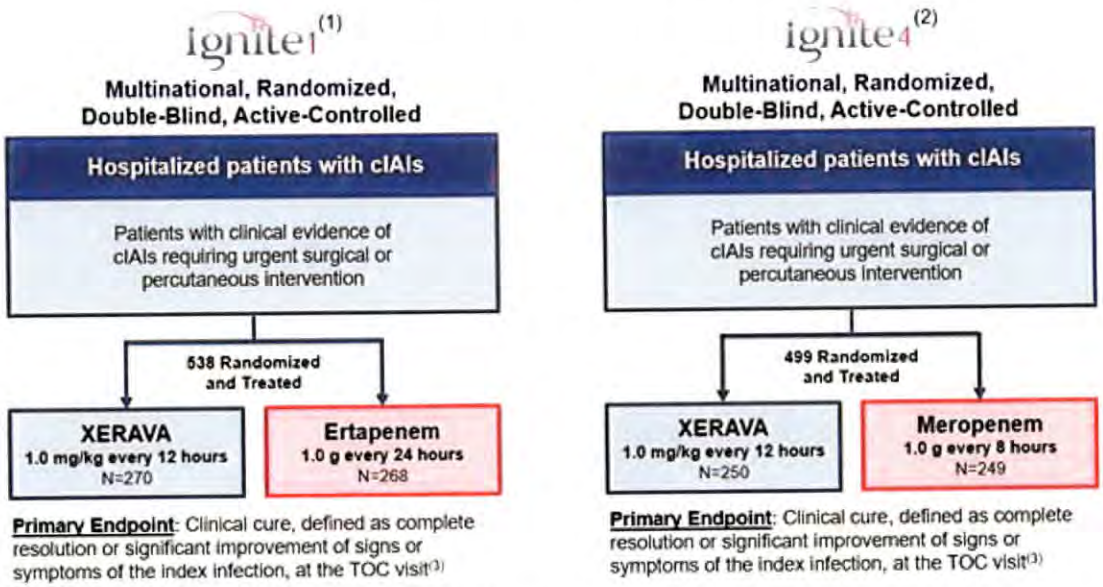
Investigating Gram-negative Infections Treated with Eravacycline ("IGNITE")

XERAVA was approved by the FDA and the EC based on the results of IGNITE1 and IGNITE4, which were published in *JAMA Surgery* in March 2017 and *Clinical Infectious Diseases* in December 2018, respectively.

IGNITE1 was a multinational, randomized, double-blind, active-controlled study in 538 patients with clinical evidence of cIAIs requiring urgent surgical or percutaneous intervention who received either XERAVA or ertapenem. The primary endpoint was clinical cure, defined as complete resolution or significant improvement of signs or symptoms of the index infection, at the test of cure ("TOC") visit. The TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered.

IGNITE4 was a multinational, randomized, double-blind, active controlled study in 499 patients with clinical evidence of cIAIs requiring urgent surgical or percutaneous intervention who received either XERAVA or meropenem. The primary endpoint was clinical cure, defined as complete resolution or significant improvement of signs or symptoms of the index infection, at the TOC visit. The TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered.

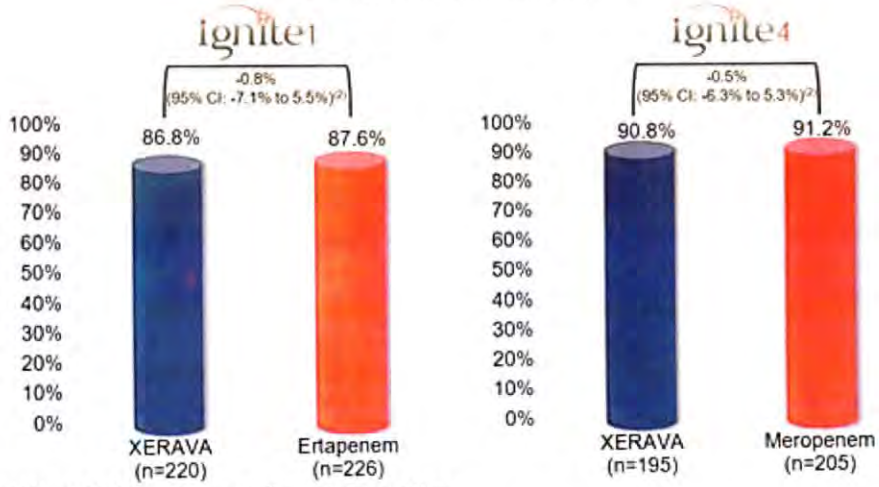
IGNITE1 and IGNITE4 Study Design



(1) Solomkin et al, *JAMA Surgery* 2017; 152(3):224-232
(2) Solomkin et al, *Clinical Infectious Diseases* 2018; 69(6):921-9
(3) TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered

XERAVA demonstrated statistical noninferiority in clinical cure rate in the micro-ITT population, which included all randomized subjects who had baseline bacterial pathogens that caused cIAIs and against at least one of which the investigational drug has *in vitro* (in a test tube) antibacterial activity (N=846).

Primary Endpoint: Clinical Cure Rate(1)



(1) XERAVA FDA prescribing information

(2) Noninferiority margins of 10% and 12.5% were used for IGNITE1 and IGNITE4, respectively

Clinical cure rates across patients with gram-negative, gram-positive and anaerobic pathogens, including those with resistant strains, are shown in the following tables.

Clinical Cure Rates at TOC by Selected Baseline Pathogens in the Micro-ITT Population(1)

	XERAVA N=415 n/N1	Comparators[2] N=431 n/N1
Enterobacteriaceae	271/314 (86.3%)	289/325 (88.9%)
Citrobacter freundii	19/22 (86.4%)	8/10 (80.0%)
Enterobacter cloacae complex	17/21 (81.0%)	23/24 (95.8%)
Escherichia coli	220/253 (87.0%)	237/266 (89.1%)
Klebsiella oxytoca	14/15 (93.3%)	16/19 (84.2%)
Klebsiella pneumoniae	37/39 (94.9%)	42/50 (84.0%)
Enterococcus faecalis	45/54 (83.3%)	47/54 (87.0%)
Enterococcus faecium	38/45 (84.4%)	48/53 (90.6%)
Staphylococcus aureus	24/24 (100.0%)	12/14 (85.7%)
Streptococcus anginosus group[3]	79/92 (85.9%)	50/59 (84.7%)
Anaerobes[4]	186/215 (86.5%)	194/214 (90.7%)

N=Number of subjects in the micro-ITT Population; N1=Number of subjects with a specific pathogen; n=Number of subjects with a clinical cure at the TOC visit

(1) XERAVA FDA prescribing information

(2) Comparators included ertapenem and meropenem for IGNITE1 and IGNITE4, respectively

(3) Includes *Streptococcus anginosus, Streptococcus constellatus, and Streptococcus intermedius*

(4) Includes *Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Parabacteroides distasonis*

XERAVA Demonstrated High Clinical Cure Rates Against Resistant Pathogens[1]

	XERAVA N=415 n/N1	Comparators[2] N=431 n/N1
Enterobacteriaceae	271/314 (86.3%)	289/325 (88.9%)
CEPH-R	43/48 (89.6%)	40/45 (88.9%)
ESBL confirmed	32/36 (88.9%)	25/29 (86.2%)
Carbapenamase[3]	1/1 (100.0%)	2/3 (66.7%)
MDR	40/46 (87.0%)	29/32 (90.6%)
Acinetobacter baumannii	13/13 (100.0%)	7/7 (100.0%)
CEPH-R	13/13 (100.0%)	5/5 (100.0%)
ESBL confirmed	5/5 (100.0%)	1/1 (100.0%)
Carbapenamase[3]	2/2 (100.0%)	4/4 (100.0%)
MDR	12/12 (100.0%)	5/5 (100.0%)

CEPH-R=cephalosporin-resistant; ESBL=extended-spectrum β-lactamases; MDR=multidrug resistance; N=Number of subjects in the micro-ITT Population; N1=Number of subjects with a specific pathogen; n=Number of subjects with a clinical cure at the TOC visit

(1) Ditch et al, 2018 ASM Microbe Annual Meeting

(2) Comparators included ertapenem and meropenem for IGNITE1 and IGNITE4, respectively

(3) Data on file from IGNITE1 and IGNITE4 micro-ITT population

The most common adverse reactions that were reported in XERAVA-treated patients in IGNITE1 and IGNITE4 were infusion site reactions.

Selected Adverse Reactions Reported in ≥1% of Patients Receiving XERAVA(1)

	XERAVA (N=520)	Comparators[2] (N=517)
Infusion site reactions[3]	40 (7.7%)	10 (1.9%)
Nausea	34 (6.5%)	3 (0.6%)
Vomiting	19 (3.7%)	13 (2.5%)
Diarrhea	12 (2.3%)	8 (1.5%)
Hypotension	7 (1.3%)	2 (0.4%)
Wound dehiscence	7 (1.3%)	1 (0.2%)

(1) XERAVA FDA prescribing information
(2) Comparators included ertapenem and meropenem for IGNITE1 and IGNITE4, respectively
(3) Infusion site reactions include: catheter/vessel puncture site pain, infusion site extravasation, infusion site hypoaesthesia, infusion/injection site phlebitis, infusion site thrombosis, injection site/vessel puncture site erythema, phlebitis, phlebitis superficial, thrombophlebitis, and vessel puncture site swelling

Product Candidates

In connection with the acquisition of Tetraphase, we acquired the following product candidates that are in early stage clinical or preclinical development: (1) TP-6076, an IV formulation of a fully synthetic fluorocycline derivative for the treatment of certain multidrug-resistant gram-negative bacteria; (2) TP-271, an IV and oral formulation of a fully synthetic fluorocycline for the treatment of respiratory disease caused by bacterial biothreat and antibiotic-resistant public health pathogens, as well as bacterial pathogens associated with community-acquired bacterial pneumonia; and (3) TP-2846, an IV formulation of a tetracycline for the treatment of acute myeloid leukemia. At this time, there are no active studies nor anticipated future studies for any of these product candidates. We intend to seek out-licensing opportunities for these product candidates; however, at this time, we are unable to predict the likelihood of successfully out-licensing any of these product candidates.

Sales and Marketing Organization

La Jolla employs an experienced sales and marketing team dedicated to the commercialization of GIAPREZA and XERAVA. As of December 31, 2020, this team consisted of 39 professionals, including 29 critical care specialists.

Customers

During the year ended December 31, 2020, 521 hospitals in the U.S. purchased GIAPREZA. During the year ended December 31, 2020, 750 hospitals and other healthcare organizations in the U.S. purchased XERAVA. Hospitals and other healthcare organizations purchase our products through a network of specialty and wholesale distributors. We do not believe that the loss of any one of these distributors would significantly impact our ability to distribute GIAPREZA or XERAVA, as we expect that sales volume would be absorbed by the remaining distributors. Due to the relatively short lead-time required to fill orders for GIAPREZA and XERAVA, backlog is not material to our business.

Competition

Catecholamines (primarily norepinephrine), which are available as generics and inexpensive, are typically used first line to treat distributive shock, while Vasostrict® (Endo International plc) is typically used second line. In the randomized, Phase 3 study ATHOS-3, GIAPREZA demonstrated clinical benefit in patients who were not adequately responding to available vasopressors, including catecholamines and Vasostrict. GIAPREZA's principal competition as a treatment in patients not adequately responding to available vasopressors is the use of these same vasopressors, particularly norepinephrine, at increased doses. If we are unable to successfully change treatment practices, the commercial prospects for GIAPREZA will be limited, and our business will suffer.

XERAVA competes with a number of antibiotics that are currently marketed for the treatment of cIAI and other multidrug resistant infections, including: AVYCAZ (ceftazidime and avibactam, marketed by AbbVie Inc.); MERREM IV® (meropenem, marketed by AstraZeneca PLC); PRIMAXIN® (imipenem and cilastatin, marketed by Merck & Co., Inc.); RECARBRIO™ (imipenem, cilastatin, and relebactam, marketed by Merck & Co., Inc.); TYGACIL® (tigecycline, marketed by Pfizer Inc.); VABOMERE™ (meropenem and vaborbactam, marketed by Melinta Therapeutics, Inc.); ZERBAXA® (ceftolozane and tazobactam, marketed by Merck & Co., Inc.); ZOSYN® (piperacillin and tazobactam, marketed by Pfizer Inc.); and current and future generic versions of marketed antibiotics. If we are unable to successfully change treatment practices, the commercial prospects for XERAVA will be limited, and our business will suffer.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of GIAPREZA or XERAVA. We rely on third-party manufacturers to produce GIAPREZA and XERAVA and expect to continue to do so to meet our development and commercial needs. In all of our manufacturing agreements, we require that contract manufacturers produce active pharmaceutical ingredients ("APIs") and drug products in accordance with the FDA's current Good Manufacturing Practices ("cGMPs") and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to GIAPREZA and XERAVA. The long-term commercial success of GIAPREZA and XERAVA will depend in part on the ability of our contract manufacturers to supply cGMP-compliant API and drug product without interruption.

Regulatory Exclusivity

GIAPREZA and XERAVA are New Chemical Entities ("NCEs") approved by the FDA. In the U.S., NCEs approved by the FDA are eligible for market exclusivity under the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA"), which can prevent the approval of generic versions of the NCE for 5 to 7.5 years from the date of the initial approval of the NCE. Specifically, the FDCA provides a 5-year period of marketing exclusivity within the U.S. to the applicant that gains approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all of the data required for approval. However, an application may be submitted 4 years after the NDA approval of the NCE if it contains a certification of patent invalidity or non-infringement. This certification will trigger an automatic stay in the approval of any generic competition until the earlier of: (a) 30 months from the certification; or (b) a court ruling of patent invalidity or non-infringement for the relevant patents. In the absence of a court ruling, the 30-month stay will be extended by such amount of time (if any) that is required for 7.5 years to have elapsed from the date of NDA approval of the NCE.

Under the Generating Antibiotic Incentives Now ("GAIN") provisions of the Food and Drug Administration Safety and Innovation Act ("FDASIA"), the FDA may designate a product as a qualified infectious disease product ("QIDP"). In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections. We obtained a QIDP designation for the IV formulation of XERAVA for cIAI in July 2013. Upon approving an application for a QIDP, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a five-year exclusivity period awarded for an NCE. This extension is in addition to any pediatric exclusivity extension awarded. XERAVA has been awarded this five-year exclusivity under FDASIA.

Intellectual Property

Patents and other proprietary rights are important to our business. As of February 19, 2021, the intellectual property portfolio relating to GIAPREZA included 12 issued U.S. patents, 8 pending U.S. patent applications, 8 issued foreign patents, 45 pending foreign patent applications, and 1 international patent application filed under the Patent Cooperation Treaty ("PCT"). The issued U.S. patents, and patents that may issue from the pending U.S. patent applications, will expire between 2029 and 2038, absent any disclaimers, extensions, or adjustments of patent term. The foreign patents, and patents that may issue from the pending foreign patent applications, will expire between 2034 and 2037, absent any disclaimers, extensions, or adjustments of patent term. Patents that may issue from applications claiming priority to the PCT application will expire in 2040, absent any disclaimers, extensions, or adjustments of patent term.

As of February 19, 2021, we owned 2 issued U.S. patents, 1 pending U.S. patent application, 17 issued foreign patents and 5 pending foreign patent applications relating to XERAVA. The issued U.S. patents, and the patent that may issue from the pending U.S. patent application, will have an expiration date of August 7, 2029, absent any disclaimers, extensions or adjustments of patent term. The term of one of the U.S. patents has received 508 days of patent term adjustment. The foreign patents, and patents that may issue from the pending foreign applications, will likewise have an expiration date of August 7, 2029, absent any disclaimers, extensions or adjustments of patent term.

As of February 19, 2021, we also filed applications for Supplementary Protection Certificates based on European Patent No. 2323972 covering the composition of matter and use of XERAVA. Some applications have been granted and others are pending.

As of February 19, 2021, we also owned 1 pending U.S. patent application and 10 pending foreign patent applications that relate to crystalline forms of eravacycline. Any U.S. patent that may issue from the pending patent application will expire in 2037 absent any disclaimers, extensions, or adjustments of patent term. Likewise, any foreign patents that may issue from the pending foreign patent applications will expire in 2037.

The following table summarizes our issued patents and pending applications for GIAPREZA, XERAVA and other tetracycline-related intellectual property.

	United States			Foreign (including PCT)		
Description	Issued	Pending	Expiration	Issued	Pending	Expiration
GIAPREZA	12	8	2029–2038	8	45	2034–2040
XERAVA	2	2	2029–2037	17	15	2029–2037
Other	8	2	2029–2040	52	32	2029–2040

Material Contracts

See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations."

Government Regulation

Pharmaceutical products, including GIAPREZA and XERAVA, are subject to extensive government regulation. In the U.S., the FDA regulates pharmaceutical products. FDA regulations govern the testing, research and development activities, manufacturing, quality, storage, advertising, promotion, labeling, sale and distribution of pharmaceutical products. Accordingly, there is a rigorous process for the approval of new drugs and ongoing oversight of marketed products. We may also be subject to foreign regulatory requirements governing clinical studies and drug products if products are tested or marketed abroad. The approval process outside of the U.S. varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

Regulation in the U.S.

The FDA testing and approval process requires substantial time, effort and financial resources. We cannot assure you that any of our product candidates will ever obtain approval. The FDA approval process for new drugs includes, without limitation:

- preclinical studies;
- submission in the U.S. of an IND for clinical studies conducted in the U.S.;
- adequate and well-controlled clinical studies to establish safety and efficacy of the product;
- review and approval of an NDA in the U.S.; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's cGMP regulations.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements on us and our third-party manufacturers. Even after regulatory approval is obtained, under certain circumstances, such as later discovery of previously unknown safety risks, the FDA can withdraw approval or subject the drug to additional restrictions.

The FDA closely regulates the marketing and promotion of drugs. Drugs may only be marketed in a manner consistent with their FDA-approved labeling. Approval may be subject to post-marketing surveillance and other record-keeping and reporting obligations. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

The failure to comply with FDA's requirements may result in adverse publicity, warning letters, corrective advertising, restrictions on marketing or manufacturing, refusals to review pending product applications, refusals to permit the import or export of products, seizures, injunctions, and civil and criminal penalties.

Third-party Payor Coverage and Reimbursement

In the U.S. and most major foreign markets, drugs like GIAPREZA and XERAVA that are administered in the hospital must be purchased by the hospital and generally are not reimbursed by third-party payors. Hospitals instead are reimbursed for patient cases based on patients' diagnosed conditions under the U.S. Medicare diagnosis-related group ("DRG") system or other like systems for non-Medicare patients in the U.S. and in most major foreign markets. Adoption of new drugs that are administered in the hospital generally occurs more slowly than adoption of new drugs that are taken on an outpatient basis, which generally are paid for by third-party payors.

U.S. Health Care Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the health care industry. These laws may impact, among other things, our sales and marketing efforts. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example gifts, cash payments, donations, the furnishing of supplies or equipment, waivers of payment, ownership interests, and providing any item, service or compensation for something other than fair market value.
- Federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent. Although we may not submit claims directly to payors, manufacturers can be held liable under these laws in a variety of ways. These include: providing inaccurate billing or coding information to customers; improperly promoting a product's off-label use; violating the federal Anti-Kickback Statute; or misreporting pricing information to government programs.
- Provisions of the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services.
- The federal Physician Payment Sunshine Act requirements, under the Patient Protection and Affordable Care Act ("PPACA"), which require manufacturers of certain drugs and biologics to track and report to U.S. Centers for Medicare & Medicaid Services ("CMS") payments and other transfers of value they make to U.S. physicians and teaching hospitals as well as physician ownership and investment interests in the manufacturer.
- Provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations ("HITECH"), which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information.
- Section 1927 of the Social Security Act, which requires that manufacturers of drugs and biological products covered by Medicaid report pricing information to CMS on a monthly and quarterly basis, including the best price available to any customer of the manufacturer, with certain exceptions for government programs, and pay prescription rebates to state Medicaid programs based on a statutory formula derived from reported pricing information.
- State law equivalents of each of the above federal laws, such as the recently effective California Consumer Privacy Act, many of which differ from each other in significant ways and may not have the same effect, which complicates our compliance efforts.

Regulation in Non-U.S. Jurisdictions

In addition to regulations in the U.S., we may be subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of GIAPREZA, XERAVA or future products. For example, clinical studies conducted in the European Union must be done under a clinical trial application ("CTA"), which is usually supported by an Investigational Medicinal Product Dossier ("IMPD"), and the oversight of ethics committees. If we market GIAPREZA in foreign countries, we also will be subject to foreign regulatory requirements governing marketing approval for pharmaceutical products. The requirements governing the conduct of clinical studies, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the regulatory authorities of foreign countries must be obtained before marketing the product in those countries. The approval process varies from country to country, and the time required for such approvals may differ substantially from that required for FDA approval. Foreign regulatory approval processes involve many of the risks associated with FDA marketing approval discussed above. There is no assurance that any FDA approval of any of our product candidates will result in similar foreign approvals or vice versa. The process for clinical studies in the European Union and other countries is similar, and studies are heavily scrutinized by the designated ethics committees and regulatory authorities. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to health care professionals and entities.

In Europe, the European Union General Data Protection Regulation (2016/679) ("GDPR") contains provisions specifically directed at the processing of health information. The GDPR provides for potentially significant sanctions and contains extraterritoriality measures intended to bring non-EU companies under the regulation. In addition to the GDPR, individual countries in Europe and elsewhere in the world have enacted similar data privacy legislation. This legislation imposes increased compliance obligations and regulatory risk, including the potential for significant fines for noncompliance.

Other Laws and Regulations

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the U.S. Securities and Exchange Commission ("SEC") and the regulations of the Nasdaq Capital Market, on which our shares of common stock are traded. We are also subject to various laws and regulations relating to safe working conditions, laboratory practices and the experimental use of animals.

Human Capital

As of December 31, 2020, we employed 59 full-time equivalent employees. None of our employees are represented by labor unions or covered by collective bargaining agreements, and we consider our relations with our employees to be good. We also hire consultants and contract with third parties, as needed, to provide additional resources to support our business activities.

Our key human capital management objectives are to identify, recruit, integrate, retain and motivate our new and existing employees. We believe that our compensation and benefit programs are appropriately designed to attract and retain qualified talent. Employees receive an annual base salary and are eligible to earn performance-based cash bonuses. To create and maintain a successful work environment, we offer a comprehensive package of additional benefits that support the physical and mental health and wellness of all of our employees and their families. Additionally, we grant equity awards in order to allow for directors, officers, employees and consultants of La Jolla to share in the performance of the Company.

Corporate and Other Information

The Company was incorporated in Delaware in 1989 and reincorporated in California in 2012. Effective April 15, 2021, our principal executive offices will be located at 201 Jones Road, Suite 400, Waltham, Massachusetts 02451. Our telephone number is (617) 715-3600. Shares of our common stock trade on the Nasdaq Capital Market under the symbol "LJPC." Our website address is www.ljpc.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

We file electronically with the SEC our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.ljpc.com, free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

June 7, 2021

Via Fed Ex

To Whom It May Concern:

On behalf of Tetraphase Pharmaceuticals, Inc., attached is Tetraphase Pharmaceuticals, Inc.'s application.

Tetraphase Pharmaceuticals, Inc. operates as a clinical-stage life science company with a synthetic chemistry technology platform that has the potential to address the global health crisis caused by antibiotic resistance.

Tetraphase Pharmaceuticals, Inc. is a "Virtual Manufacturer" whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from Tetraphase Pharmaceuticals, Inc.'s office. Tetraphase Pharmaceuticals, Inc.'s product is not a controlled substance. Accordingly, Tetraphase Pharmaceuticals, Inc. is not required to obtain a DEA registration.

I hope this narrative is helpful as you review Tetraphase Pharmaceuticals, Inc.'s application. If you have a question regarding this application, please contact me at (614) 620-6898 or via email at krista.jones@twolabs.com. Please also address all written communication to me. My address is 210 Victorian Drive, Commercial Point, OH 43116.

Thank you in advance for your consideration.

Krista Jones
Sr. Licensing Analyst
PharmaLicense

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☒ Ownership Change (Provide current license number if making changes: WH 02961)
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Organon LLC

Physical Address: 2000 Galloping Hill Rd, Building K-15, 4th Floor

City: Kenilworth State: NJ Zip Code: 07033

Telephone Number: 908-740-4000 Fax Number: N/A

Toll Free Number: N/A

E-mail: nicole.steiner@organon.com Website: N/A

Facility Manager: Karen M. Tatarowicz

Professional qualifications and experience of facility manager: See Attachment C

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☒ Practitioners ☒ Hospitals ☒ Wholesalers
☐ Other:

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Hypodermic Devices
☐ Poisons or Chemicals
☐ Veterinary Legend Drugs
☒ Controlled Substances (include copy of DEA) See Attachment D
☐ Other:

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: CARDINAL HEALTH
Address: 600 N 83RD AVE / TOLLESON AZ 85353-9257

Name: AMERISOURCEBERGEN DRUG CORP PHOENIX
Address: 7775 W BUCKEYE RD, STE 150 / PHOENIX AZ 85043-4204

Name: HENRY SCHEIN INC
Address: 255 VISTA BLVD / SPARKS NV 89434-9504

Name: ASD SPECIALITY HEALTHCARE
Address: 1195 TRADEMARK DR, STE 102 / RENO NV 89521-6002

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Faye Brown
Print Name of Authorized Person

4/9/2021
Date

Board Use Only	Date Processed:	Amount: $500 Check # 900000012

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Organon & Co.

Mailing Address: 30 Hudson Street, 33rd floor

City: Jersey City State: NJ Zip: 07302

Telephone: 551-430-6225 Fax: N/A

Contact Person: Faye Brown

For any corporation non-publicly traded, disclose the following: See Attachment E

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors See Attachment F

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See Attachment A

Attachment

Organon LLC is currently a wholly owned subsidiary of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. Please be advised that as of June 2, 2021, Organon LLC will become a wholly owned subsidiary of Organon & Co.

Attachment A

Letter of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ORGANON LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF JANUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

7803284 8300

SR# 20210085968

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202267666

Date: 01-12-21

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF "OBS PHARMA LLC", FILED IN THIS OFFICE ON THE SIXTEENTH DAY OF JANUARY, A.D. 2020, AT 11:11 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

7803284 8100
SR# 20200326315

Authentication: 202201514
Date: 01-16-20

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:11 AM 01/16/2020
FILED 11:11 AM 01/16/2020
SR 20200326315 - File Number 7803284

Execution Version

STATE OF DELAWARE
LIMITED LIABILITY COMPANY
CERTIFICATE OF FORMATION
OF
OBS PHARMA LLC

The undersigned, being an authorized person for purposes of executing this Certificate of Formation on behalf of OBS Pharma LLC, a Delaware limited liability company, desiring to comply with the requirements of 6 Del. C. §18-201 and the other provisions of the Delaware Limited Liability Company Act, 6 Del. C. §18-201, et seq. hereby certifies as follows:

1. Name. The name of the limited liability company is OBS Pharma LLC (the "**Company**").

2. Registered Office and Registered Agent. The address of the Company's registered office in the State of Delaware is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of the Company's registered agent at such address is The Corporation Trust Company.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this January 16, 2020.

By: _____
Faye C. Brown
Authorized Person

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "OBS PHARMA LLC", CHANGING ITS NAME FROM "OBS PHARMA LLC" TO "ORGANON LLC", FILED IN THIS OFFICE ON THE TWENTY-SEVENTH DAY OF MARCH, A.D. 2020, AT 6:31 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

7803284 8100
SR# 20202433577

Authentication: 202676811
Date: 03-30-20

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 06:31 PM 03/27/2020
FILED 06:31 PM 03/27/2020
SR 20202433577 - File Number 7803284

STATE OF DELAWARE
LIMITED LIABILITY COMPANY

AMENDMENT TO CERTIFICATE OF FORMATION
OF
OBS PHARMA LLC

This Amendment to Certificate of Formation of OBS Pharma LLC (the "**Company**") is being duly executed and filed by the undersigned, to amend the Certificate of Formation of OBS Pharma LLC as provided under the Delaware Limited Liability Company Act (6 Del. C. § 18-202), as amended.

FIRST: The name of the limited liability company is OBS Pharma LLC.

SECOND: The Certificate of Formation of the Company is hereby amended by deleting the first article thereof in its entirety and inserting in lieu thereof the following:

The name of the limited liability company is Organon LLC.

IN WITNESS WHEREOF, the undersigned has executed this Amendment to Certificate of Formation of OBS Pharma LLC this 27th day of March, 2020.

OBS Pharma LLC

By: /s/ Jon Filderman
Name: Jon Filderman
Title: Secretary

Attachment B

Resident State License

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0742869

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

2000 GALLOPING HILL RD BLDG K15 FL4 KENILWORTH, NJ 07033-

Reg. No.
5005799

ORGANON LLC
MAIL CODE: F30, #F4200E
2000 GALLOPING HILL RD BLDG K15 FL4
KENILWORTH, NJ 07033-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2022

Establishment Copy

Attachment C

Facility Manager Resume

Pr Proprietary

Karen M Tatarowicz
[redacted] N 9th Street ▪ Perkasie, PA, 18944 ▪ [redacted] ▪ **Email: karen.tatarowicz@organon.com**

EDUCATION

Villanova University, Villanova, PA 19085
Bachelor of Chemical Engineering

EMPLOYMENT

Effective 02/21 ***Organon LLC (a wholly owned subsidiary of Merck Sharp & Dohme Corp.)***. **D&L Operations Lead for USA** ▪ Operation's lead supporting US distribution. Coordinates team with oversight of day to day operations to supply US and Puerto Rico.

5/16-present ***Merck & Co., Inc.*** **Associate Director, US Commercial Operations**▪ Operation's lead supporting US distribution at 3PL locations. Coordinates team with oversight of day to day operations for the two locations that supply the US and Puerto Rico. Manages relationship with 3rd party and collaborates with a cross-functional team including order management, planning, quality and technology to ensure consistent reliable supply to our customers

5/14-5/16 ***Merck & Co., Inc.*** **Sr. Specialist -Logistics**▪ Technical lead supporting cold chain management, warehouse operations, and 3rd party warehouse/distribution centers. Interact with external partners/ third party logistics to discuss GDP compliance issues, perform technical review on their investigations and CAPAs and improve shipping process.

4/10-5/14 ***Merck & Co., Inc.*** **Production Lead** ▪ Lead for Vaccine packaging in West Point Packaging Operations. Responsible for Compliance, Supply, Strategy and Profit Plan. Team includes coaches, operations personnel, and cross functional team of engineers and quality.

7/06-4/10 ***Merck & Co., Inc.*** **Sr. Production Supervisor** ▪ Direct supervision and manufacturing responsibility for several of the primary vaccine packaging lines. Specifically, motivating the workforce, work performance, schedule execution, equipment and area preparation and administration of personnel policies and procedures.

1/01-3/03 ***Air Products and Chemicals, Inc.*** **Manager, Emerging Technology Identification** ▪ I supervised a team that provided early access to external technologies by alerting researchers within the company and leading collaborative effort to bring new technologies into the company.

4/94-12/00 ***Air Products and Chemicals, Inc.*** **External Technology Specialist** ▪ I identified new technology developments that would enhance the company portfolio. This position included traveling to universities, companies and technology fairs to seek out emerging technologies and develop contacts within the industry.

5/89-6/93 ***Air Products and Chemicals, Inc.*** **Senior Principal Safety Engineer** ▪ I led technical teams to complete process safety hazard reviews. Also, I developed training materials and trained engineering staff members on how to complete safety reviews using several techniques; HAZOP, Consequence Analysis, and Fault Tree Analysis.

6/82-1/88 ***Air Products and Chemicals, Inc.*** **Senior Project Engineer** ▪ I managed capital projects, ranging from $200,000 to $7,000,000. Responsibilities included preparing financial justification and presenting new projects to upper management for approval, estimating total project cost, scheduling, preparing specifications and bid drawings for design build work, conducting bid conferences, finalizing plans for construction, and overseeing construction and start-up.

PERSONAL INTERESTS

Hiking, Pickleball, volunteering: Doylestown Hospital, Children's Hospital of Philadelphia, and the ALS Association.

Attachment D

Regarding DEA Registration

Organon LLC has no products that are classified as federally controlled substances. Organon LLC does not hold a DEA license. One product, human chorionic gonadotropin (HCG), is classified as a Schedule III controlled drug by the Nevada Board of Pharmacy. Organon LLC does not handle prescription drugs at any time either for physical manufacturing or distribution.

Attachment E

Business Model

Organon LLC does not handle prescription drugs at any time either for physical manufacturing or distribution. However, they do maintain product ownership and are responsible for the oversight and sale of products. Organon utilizes a NABP accredited Drug Distributor, third-party logistics provider to warehouse and distribute its prescription drugs into the fifty states and the District of Columbia.

Attachment F

List of Corporate Officers

Title:	Vice President, Finance
Name:	Daniel S. Fetzer
Title:	Vice President and Assistant Treasurer
Name:	Joseph B. Promo
Title:	Assistant Treasurer
Name:	Kara A. Rogers
Title:	Assistant Secretary
Name:	Geralyn S. Ritter
Title:	Assistant Secretary
Name:	Faye Brown

Attachment G

Regarding the Fingerprint Submission

The required fingerprint cards were submitted separately to your office on Thursday, April 8, 2021 via UPS Tracking #: **1Z8AT763NT90562855**

Attachment H

Bond

Pr Proprietary

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

IRREVOCABLE STANDBY LETTER OF CREDIT

NAME OF FINANCIAL INSTITUTION: BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE
CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

DATED: APRIL 12, 2021

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF ORGANON LLC, WE BNP PARIBAS, ACTING THROUGH ITS NEW YORK BRANCH HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF $ 100,000.00 USD.

2. THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. PURSUANT TO NRS 639.515(4), UPON THE IMPOSITION OF ANY FINES OR COSTS BY THE BOARD AGAINST THE APPLICANT/LICENSEE, THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN THE FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT BNP PARIBAS C/O BNP PARIBAS RCC, INC., NEWPORT TOWER - SUITE 188, 525 WASHINGTON BLVD., JERSEY CITY, NJ 07310 ATTN: TRADE FINANCE SERVICES.

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY COURIER OR REGISTERED MAIL, RETURN RECEIPT REQUESTED.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL
SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL GIVE THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND AWAIT FURTHER INSTRUCTIONS.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED UPON RECEIPT BY US OF A CERTIFICATE OF CANCELLATION IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD OR ON APRIL 12, 2022 WHICHEVER SHALL OCCUR FIRST.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT BNP PARIBAS C/O BNP PARIBAS RCC, INC., NEWPORT TOWER SUITE 188, 525 WASHINGTON BLVD., JESREY CITY, NJ 07310 ATTN: TRADE FINANCE SERVICES AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED OR ASSIGNED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT IS ISSUED SUBJECT TO THE UNIFORM CUSTOMS AND PRACTICE FOR DOCUMENTARY CREDITS (2007 REVISION), INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 600.

THEREFORE, BNP PARIBAS HAS EXECUTED AND DELIVERED THIS IRREVOCABLE STANDBY LETTER OF CREDIT TO THE BOARD AS OF THE 12TH DAY OF APRIL, 2021.

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Reference No.: 04162669

CERTAIN ADMINISTRATIVE SERVICES FOR BNP PARIBAS MAY BE PROVIDED BY BNP PARIBAS RCC, INC., BNP PARIBAS, THROUGH ITS CANADA BRANCH, OR ANY DIRECT OR INDIRECT MAJORITY OWNED SUBSIDIARY OF BNP PARIBAS.

BNP PARIBAS

BY: _____
NAME: Teresa D'Adamo
TITLE: Vice President.

BY: _____
NAME: BEATRICE LEUNG
TITLE: AVP

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

ATTACHMENT A

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
(775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV.GOV

CERTIFICATE OF DRAWING

NAME OF FINANCIAL INSTITUTION (ISSUER): BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE

CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206 RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. A LAWFUL ORDER IMPOSING FINES AND/OR COSTS AGAINST THE APPLICANT/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF $ _____.

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS TO BE RECEIVED BY THE BOARD AT THE



BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Page: 5
Reference No.: 04162669

ABOVE ADDRESS NO LATER THAT 5:00 PM NEW YORK TIME ON THE ____ DAY OF ____ 20__.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF DRAWING ON THIS DAY OF _____, 20__.

NEVADA STATE BOARD OF PHARMACY

BY: _____
LARRY L. PINSON, PHARM.D.
EXECUTIVE SECRETARY



BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Page: 6
Reference No.: 04162669

ATTACHMENT B

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
(775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV.GOV

CERTIFICATE FOR CANCELLATION

NAME OF FINANCIAL INSTITUTION (ISSUER): BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE

CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED, OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPRIATE.

2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE-REFERENCED CREDIT.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF CANCELLATION ON THIS DAY OF _____, 20___.

NEVADA STATE BOARD OF PHARMACY

BY: _____
LARRY L. PINSON, PHARM.D.
EXECUTIVE SECRETARY

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

IRREVOCABLE STANDBY LETTER OF CREDIT

NAME OF FINANCIAL INSTITUTION: BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE
CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

DATED: APRIL 12, 2021

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF ORGANON LLC, WE BNP PARIBAS, ACTING THROUGH ITS NEW YORK BRANCH HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF $ 100,000.00 USD.

2. THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. PURSUANT TO NRS 639.515(4), UPON THE IMPOSITION OF ANY FINES OR COSTS BY THE BOARD AGAINST THE APPLICANT/LICENSEE, THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN THE FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT BNP PARIBAS C/O BNP PARIBAS RCC, INC., NEWPORT TOWER - SUITE 188, 525 WASHINGTON BLVD., JERSEY CITY, NJ 07310 ATTN: TRADE FINANCE SERVICES.

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY COURIER OR REGISTERED MAIL, RETURN RECEIPT REQUESTED.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL
SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL GIVE THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND AWAIT FURTHER INSTRUCTIONS.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED UPON RECEIPT BY US OF A CERTIFICATE OF CANCELLATION IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD OR ON APRIL 12, 2022 WHICHEVER SHALL OCCUR FIRST.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT BNP PARIBAS C/O BNP PARIBAS RCC, INC., NEWPORT TOWER SUITE 188, 525 WASHINGTON BLVD., JESREY CITY, NJ 07310 ATTN: TRADE FINANCE SERVICES AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED OR ASSIGNED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT IS ISSUED SUBJECT TO THE UNIFORM CUSTOMS AND PRACTICE FOR DOCUMENTARY CREDITS (2007 REVISION), INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 600.

THEREFORE, BNP PARIBAS HAS EXECUTED AND DELIVERED THIS IRREVOCABLE STANDBY LETTER OF CREDIT TO THE BOARD AS OF THE 12TH DAY OF APRIL, 2021.

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Page: 3
Reference No.: 04162669

CERTAIN ADMINISTRATIVE SERVICES FOR BNP PARIBAS MAY BE PROVIDED BY BNP PARIBAS RCC, INC., BNP PARIBAS, THROUGH ITS CANADA BRANCH, OR ANY DIRECT OR INDIRECT MAJORITY OWNED SUBSIDIARY OF BNP PARIBAS.

BNP PARIBAS

BY: _____
NAME: Teresa D'Adamo
TITLE: Vice President.

BY: _____
NAME: BEATRICE LEUNG
TITLE: AVP

BNP PARIBAS

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Page: 4
Reference No.: 04162669

ATTACHMENT A

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
(775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV.GOV

CERTIFICATE OF DRAWING

NAME OF FINANCIAL INSTITUTION (ISSUER): BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE

CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206 RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. A LAWFUL ORDER IMPOSING FINES AND/OR COSTS AGAINST THE APPLICANT/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF $ _____.

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS TO BE RECEIVED BY THE BOARD AT THE

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

Page: 5
Reference No.: 04162669

ABOVE ADDRESS NO LATER THAT 5:00 PM NEW YORK TIME ON THE ____ DAY OF ____ 20__.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF DRAWING ON THIS DAY OF _____, 20__.

NEVADA STATE BOARD OF PHARMACY

BY: _____
LARRY L. PINSON, PHARM.D.
EXECUTIVE SECRETARY

BNP PARIBAS

BNP PARIBAS
CORPORATE & INSTITUTIONAL BANKING

ATTACHMENT B

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
(775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV.GOV

CERTIFICATE FOR CANCELLATION

NAME OF FINANCIAL INSTITUTION (ISSUER): BNP PARIBAS

ADDRESS: ATTN: TRADE FINANCE SERVICES, 787 SEVENTH AVENUE

CITY: NEW YORK STATE: NY ZIP: 10019

NAME OF APPLICANT/LICENSEE: ORGANON LLC

ADDRESS: 2000 GALLOPING HILL ROAD, K-15 4TH FL

CITY: KENILWORTH STATE: NJ ZIP: 07033

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 04162669

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED, OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPRIATE.

2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE-REFERENCED CREDIT.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF CANCELLATION ON THIS DAY OF _____, 20___.

NEVADA STATE BOARD OF PHARMACY

BY: _____
LARRY L. PINSON, PHARM.D.
EXECUTIVE SECRETARY

4HHH

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ Ownership Change (Provide current license number if making changes: PH 03674
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☒ Partnership - Pages 1,2,6,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Silver State Drug – Alamo

Physical Address: 414 Broadway

City: Alamo, NV State: Zip Code: 89001 Telephone: (775) 725-3515

Fax: _____ Toll Free Number: _____

E-mail: a_bleak@yahoo.com

Website: _____

Managing Pharmacist: Andrew Bleak License Number: 18263

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☒	☐ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☒	☐ Community	☒	☐ Long Term Care
☐	☐ Other: _____	☐	☒ Sterile Compounding
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding
	For the application to be complete	☐	☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☒ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Andrew Bleau

Original Signature of Person Authorized to Submit Application, no copies or stamps

Andrew Bleau

Print Name of Authorized Person

3/8/21

Date

Board Use Only	Date Processed:	Amount: 500 Check #029507

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General_____ Limited _____

List names of 4 largest partners and percentage of ownership:

Name: Andrew Bleak %: 100

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: Silver State Drug - Alamo

Mailing Address: P.O. Box 565 Panaca, NV 89042

City, State Zip Code: Alamo, NV 89001

Telephone Number: (775)725-3515 Fax Number: _____

Contact Person: Andrew Bleak

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru ~~Friday~~ Thursday 9 am 5 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Andrew Bleak

Responsible Person of Silver State Drug - Alamo

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Andrew Bleak
Print Name of Authorized Person

3/8/21
Date

Managing Pharmacist

Pharmacist Name: Andrew Bleak License #: 18263

Pharmacy Name: Silver State Drug - Alamo

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☒
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature _____ Date 3/8/21

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

1256

Date 3/17/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

Silver State Drug - Alamo
Name and Address of Establishment for Which License Is Requested

Jolly's Drug Store - Alamo
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Bleak (Last Name) | Andrew (First Name) | W. (Middle Name)

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] S. 4th St. (Present Residence Address-Street or RFD) | Panaca (City) | NV 89042 (State/Zip)

414 Broadway (Present Business Address) | Dates | ~~Caliente~~ Alamo (City) | NV ~~89008~~ 89001 (State/Zip)

Pharmacist (Occupation) | Dates 2017 - Present

Phone: Residence [redacted]

[redacted] (Date of Birth) | Cedar City, Iron, UT (Place of Birth (City, County, State)) | Business 775-725-3515

39 (Age) | [redacted] (Social Security Number or ITIN) | Male (Sex)

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Green	Brown	White	180	Slender	5'10"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No — If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single — (Married) — Separated — Divorced — Widowed — Engaged

Applicant's initial AB

A. **Current Marriage** March 6, 2004 (Date) Salt Lake City, Salt Lake, UT (City, County and State)

Spouse's full name (Maiden) Jenny Lynn Peterson SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth Cedar City, UT

Resident address [redacted] South 4th St. (Street) Panaca (City) NV (State) 89042 (Zip)

Telephone: Residence [redacted] Business .....

Spouse's employer N/A Occupation Homemaker

Address of employer ____ (Street) ____ (City) ____ (State) ____ (Zip)

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					

3. **FAMILY INFORMATION:**

A. **Children and Dependents:**

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Tanner Bleak	[redacted]	Cedar City, UT	[redacted] South 4th St.
Benson Bleak		Omaha, NE	South 4th St.

B. **Child Support Information:**

Please mark the appropriate response:

☒ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial AG AG

...T INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address

Contact person

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Nelson Lorell Bleak	[redacted]	Heaps St. Panaca, NV	Retired
Mother	Terry Wadsworth		Heaps St. Panaca, NV	Retired
Father-in-Law	Clifford Pete Peterson		[redacted] N. 6th St. Panaca, NV	Elem. Principal
Mother-in-Law	Beverly Roe		[redacted] N. 6th St. Panaca, NV	Retired

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Eric Lorell Bleak	[redacted]	[redacted] Larkspur Rd. St. George, UT	School teacher
Spouse	Karey Beckel		" "	Massage therapist
	Sylvia Lark Bleak		[redacted] Barnwood Ct. Colfax, NC	School Coordinator
Spouse	William Greene		" "	Sales Rep.
	Jared Bleak		[redacted] N. 1300 W. #36 St. George, UT	Education Consultr
Spouse	N/A			
	James Gordon Bleak		[redacted] Oak Wells Rd. Panaca, NV	Construction
Spouse	Kodi Ann Michaelson		" "	Dental Hygenist

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Panaca Elementary	Panaca, NV	1986-1995	(Yes) No
High School	Lincoln County High School	Panaca, NV	1995-1999	(Yes) No
College University	Southern Utah University	Cedar City, UT	1999-2006	(Yes) No
Other	Creighton University	Omaha, NE	2007-2011	(Yes) No

Type of degree obtained, if any Bachelor of Science / Pharm D

College or university where obtained SUU / Creighton University

Applicant's initial AB AB

- MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes → (No) →

Branch _____ Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes → No → If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? (Yes) → No →

County Lincoln State Nevada Date registered 1999

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes → (No) → If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes → (No) → If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? (Yes) → No →

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes → (No) →

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes → (No) →

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes → (No) →
If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes → (No) →
If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? (Yes) → No →
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
James Bleak	Brother	Class C Felony	Panaca, NV	2006

Applicant's initial AB AB

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ~ (No) ~ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ~ (No) ~ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
3/1981-6/2000	1023 Heaps St.	Panaca	Nevada
6/2000-6/2002	1331 Airport Fwy #305	Euless	Texas
6/2002-3/2004	12 N. 900 W.	Cedar City	Utah
3/2004-5/2006	155 W. 200 S. #7	Cedar City	Utah
5/2006-9/2006	1023 Heaps St.	Panaca	Nevada
9/2006-4/2007	1518 Bench Rd. #C11	Pocatello	Idaho
5/2007-7/2007	1023 Heaps St.	Panaca	Nevada
8/2007-5/2008	150 Arbor Ct.	Omaha	Omaha
6/2008-5/2011	224 Arbor Ct.	Omaha	Nebraska
5/2011-12/2011	461 W. Center	Snowflake	Arizona

Applicant's initial AB AB

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/2017 - Current	Dolly's Drug P.O. Box 1010 Caliente, NV 89008	
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Manager	Dispensing/Record Keeping	

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
12/2013-12/2017	Meadow Valley Pharmacy 800 N. Spring st. Caliente.	Ownership change
Title	**Description of Duties**	**Name of Supervisor**
Pharmacist	Dispensing/Record Keeping	Adam Katschke

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/2013 - 12/2013	Enterprise Pharmacy 700 E. Main	Closed
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Manager	Dispensing/Record Keeping	Andrew Bleak

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
5/2011 - 7/2013	Safeway 702 W. Hopi Dr. Holbrook, AZ	New job
Title	**Description of Duties**	**Name of Supervisor**
Pharmacist	Dispensing/Record Keeping	Dave Carrington

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
10/2007 - 5/2011	Ed's Rexall 2701 S. 10th St. Omaha, NE 68108	Graduated School
Title	**Description of Duties**	**Name of Supervisor**
Student Pharmacist	Fill prescriptions	Rob Albers

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/2006 - 4/2007	Merlin's Insulation 1040 S. Main Pocatello, ID 83204	School
Title	**Description of Duties**	**Name of Supervisor**
Worker	Install insulation	Brian Blad

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
5/2006	Meadow Valley Pharmacy 800 N. Spring St. Caliente, NV	Moved
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy tech	Fill prescriptions	Adam Katschke

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
6/2003 - 9/2005	Spring Valley State Park HC 74 Box 201 Pioche, NV	School
Title	**Description of Duties**	**Name of Supervisor**
Park aide	Assist Rangers/Collect fees	Pete Gill

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial AB AB

CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Ashel Young	Home [redacted] S. 2000 W.	Delta	UT	84624		10 years
Employer Valley Agronomics	Business				[redacted]	
Name Dirk Bigelow	Home [redacted]	Olathe St. Commerce City	CO	[redacted]		13 years
Employer Safeway	Business 2660 N. Federal Blvd.	Denver	CO		(303) 477-1470	
Name Mitchell Evers	Home [redacted]	Eldon Way Sandy	UT	84093	[redacted]	13 years
Employer Ebay	Business 583 West Ebay Way	Draper	UT		(801) 545-2276	
Name Kyson Burden	Hom [redacted]	6 1/2 W. Snowflake	AZ		[redacted]	9 years
Employer Self Employed	Business					
Name Jared Brackenbury	Home [redacted]	Ox Rd. Caliente	NV	89008	[redacted]	21 years
Employer Self Employed	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ~~No~~

If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor, Doctor, Accountant, Lawyer, Contractor, Pilot, Race horse/race dog owner, Real estate broker or salesman, Sports promoter, Securities dealer, Barber/Cosmetologist, Trainer or manager, Insurance, Gaming, Educator

Yes ~~No~~

If yes, state type, where and years held

Pharmacist Arizona 9 years

Pharmacist Nevada 8 years

Pharmacist Utah 7 years

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ~~No~~

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial AZ AZ

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ~~No~~

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ~~No~~

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? ~~Yes~~ No

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? ~~Yes~~ No

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? ~~Yes~~ No

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer ~~Yes~~ No

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? ~~Yes~~ No

Tyler Heaton - brother in law



Date of photograph 3/17/21

Applicant's initial AB

STATE OF Nevada

ss.

COUNTY OF Lincoln County

I, Andrew Bleak, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 17th day of March, 2021.
by Andrew Bleak.

Betsy Comella
Notary Public

BETSY COMELLA
Notary Public, State of Nevada
Appointment No. 16-4059-11
My Appt. Expires Nov 24, 2024

(seal)

Applicant's initial AB

See attached papers

Applicant's initial AB

Pharmacy Application Continuance

3. A.

Kenlsey Bleak	[redacted]	Omaha, NE	[redacted] South 4th St. Panaca, NV
Joel Bleak		Show Low, AZ	South 4th St. Panaca, NV
Jane Bleak		St. George, UT	South 4th St. Panaca, NV
Ivy Bleak		St. George, UT	South 4th St. Panaca, NV
Eve Bleak		St. George, UT	South 4th St. Panaca, NV

3. D.

Aaron Bleak	[redacted]	W. 1220 S. Riverton, UT	Architect
Elizabeth Reber	[redacted]		Homemaker
Jason Bleak	[redacted]	Blue Ridge Rd. Battlemountain, NV	Hospital Admin.
Judy Leavitt	[redacted]		Homemaker
Robin Bleak	[redacted]	N. 2nd St. Panaca, NV	Homemaker
Tyler Heaton	[redacted]		High School Teacher/Phamacy co-owner
Nelson Collin Bleak	[redacted]	Lilith Ave Pioche, NV	Highway Patrol Officer
Ina Marie Edgar	[redacted]		Elementary School Parapro
Jeffrey Bleak	[redacted]	Snapdragon Ladera Ranch, CA	Construction
Nathan Bleak	[redacted]	Devens Dr. Brentwood, TN	Healthcare Admin.
Zoe Clement	[redacted]		Advertising

6. C.

I was questioned regarding a bombing that was a block away from my house by state investigators.

I was questioned by pharmacy investigators regarding Meadow Valley Pharmacy fraud.

7.

12/2011-8/2013	163 N. 2nd W. Snowflake, AZ 85937
8/2013-10/2013	14 S. 275 W. Enterprise, UT 84937
10/2013-7/2014	135 S. 4th St. Panaca, NV 89042
7/2014- Present	[redacted] South 4th St. Panaca, NV 89042

8.	6/2000- 6/2002 Missionary	Mission for church Service and proselyting	Euless, TX

16-18.

Meadow Valley Pharmacy's license was surrendered and the owner, Adam Katschke, plead guilty to charges dealing with fraudulent billing.

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date 3/17/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of Pharmacy or Wholesaler

Silver State Drug - Alamo
Name and Address of Business for Which Designated Representative Is Requested

Chilly's Drug Store - Alamo
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Bleak (Last Name) | Andrew (First Name) | W. (Middle Name)

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] S. 4th St. (Present Residence Address-Street or RFD) | Panaca (City) | NV 89042 (State/Zip)

414 Broadway (Present Business Address) | Dates | Alamo (City) | NV 89001 (State/Zip)

Manager (Present Position with the Pharmacy or Wholesaler) | Dates

Phone: Residence [redacted]

Business 775-725-3515

[redacted] (Date of Birth) | Cedar City, Iron, UT. (Place of Birth (City, County, State))

39 (Age) | [redacted] (Social Security Number or ITIN) | Male (Sex)

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Green	Brown	white	180	Slender	5'10"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single Married Separated Divorced Widowed Engaged

Applicant's initial AB

A. **Current Marriage** March 6, 2004 (Date) Salt Lake City, Salt Lake, Utah (City, County and State)

Spouse's full name (Maiden) Jenny Lynn Peterson S.S. No [redacted]

Date of Birth [redacted] Place of Birth Cedar City, UT

Resident address [redacted] South 4th St. (Street) Panaca (City) NV (State) 89042 (Zip)

Telephone: Residence [redacted] Business

Spouse's employer N/A Occupation Homemaker

Address of employer (Street) (City) (State) (Zip)

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Tanner Bleak	[redacted]	Cedar City, UT	[redacted] S. 4th St. Panaca
Benson Bleak		Omaha, NE	[redacted] S. 4th St. Panaca

B. Child Support Information:

Please mark the appropriate response:

☒ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial AG AG

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address

Contact person

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Nelson Lorell Bleak	[redacted]	Heaps St. Panaca, NV	Retired
Mother	Terry Wadsworth	[redacted]	Heaps St. Panaca, NV	Retired
Father-in-Law	Clifford Pete Peterson	[redacted]	N. 6th St. Panaca, NV	Elem. Principal
Mother-in-Law	Beverly Roe	[redacted]	N. 6th St. Panaca, NV	School Teacher

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Eric Lorell Bleak	[redacted]	Larkspur Rd. St. George, UT	School teacher
Spouse	Karey Beckel		"	Massage therapist
	Sylvia Lark Bleak		Barnwood St. Colfax, NC.	School coordinator
Spouse	William Greene		"	Sales rep.
	Jared Bleak		N. 1300 W. #36 St. George, UT	Education Consultant
Spouse	N/A			
	James Gordon Bleak		Oak Wells Rd. Panaca, NV	Construction
Spouse	Kodi Ann Michaelson		"	Dental Hygienist

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Panaca Elementary	Panaca, NV	1986-1995	Yes ☒ No ☐
High School	Lincoln County High School	Panaca, NV	1995-1999	Yes ☒ No ☐
College University	Southern Utah University	Cedar City, UT	1999-2006	Yes ☒ No ☐
Other	Creighton University	Omaha, NE	2007-2011	Yes ☒ No ☐

Type of degree obtained, if any Bachelor of Science / Pharm D

College or university where obtained SUU / Creighton University

Applicant's initial AB AB

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch ..... Date of entry-active service .....

Date of separation ..... Type of discharge .....

Rating at separation ..... Serial number .....

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☒ No ☐

County Lincoln State Nevada Date registered 1999

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☒ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☒ No ☐

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒
If yes, when? ..... city, county and state .....

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒
If yes when? ..... city, county and state .....

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☒ No ☐
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
James Bleak	Brother	Class C Felony	Panaca, NV	2006

Applicant's initial AB AB

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☒ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
3/1981-6/2000	1023 Heaps St.	Panaca	Nevada
6/2000-6/2002	1331 Airport Fwy. #305	Euless	Texas
6/2002-3/2004	12 N. 900 W.	Cedar City	Utah
3/2004-5/2006	155 W. 200 S. #7	Cedar City	Utah
5/2006-9/2006	1023 Heaps St.	Panaca	Nevada
9/2006-4/2007	1518 Bench Rd. #C11	Pocatello	Idaho
5/2007-7/2007	1023 Heaps St.	Panaca	Nevada
8/2007-5/2008	150 Arbor Ct.	Omaha	Nebraska
6/2008-5/2011	224 Arbor Ct.	Omaha	Nebraska
5/2011-12/2011	461 W. center	Snowflake	Arizona

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
1/17 - Current	Jolly's Drug P.O. Box 1011 Caliente, NV 89008	8190
Title	**Description of Duties**	**Name of Supervisor**
Manager	Dispensing/Record Keeping	
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
12/2013 - 12/2017	Meadow Valley Pharmacy	8000
Title	**Description of Duties**	**Name of Supervisor**
Pharmicist	Dispensing/Record Keeping	Adam Katschke
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
8/2013 - 12/2013	Enterprise Pharmacy 700 E. Main Enterprise	540
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Manager	Dispensing/Record Keeping	Adam Katschke
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
5/2011 - 7/2013	Safeway 702 W. Hopi Dr. Holbrook, AZ	5200
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Manager	Dispensing/Record Keeping	Dave Carrington
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial AZ AZ

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Ashel Young	Home [redacted]	S. 2000 W. Delta, UT 84624			[redacted]	10 years
Employer Valley Agronomics	Business					
Name Dirk Bigelow	Home [redacted]	Olathe St. Commerce City, CO 80022			[redacted]	13 years
Employer Safeway	Business	2660 N. Federal Blvd. Denver, CO 80211			(303)477-1470	
Name Mitchell Evers	Home [redacted]	Eldon Way Sandy, UT 84093			[redacted]	13 years
Employer Ebay	Business	583 West Ebay Way Draper, UT 84020			(801)545-2276	
Name Kyson Burden	Home [redacted]	S. 6 1/2 W. Snowflake, AZ 85937			[redacted]	9 years
Employer Self employed	Business					
Name Jared Brackenbury	Home [redacted]	Ox Rd. Caliente, NV 89008			[redacted]	21 years 8/1999 - Present
Employer Self employed	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☒ No ☐

If yes, state type, where and years held

Pharmacist Arizona 9 years

Pharmacist Nevada 8 years

Pharmacist Utah 7 years

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☒ No ☐

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:
Nevada Board of Pharmacy to obtain a pharmacy license 10/2016

Applicant's initial AB AB

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? (Yes) No

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? (Yes) No

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? (Yes) No

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler (Yes) No

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? (Yes) No

Tyler Heaton - brother in law

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? (Yes) No

20. Will you be employed fulltime with the pharmacy or wholesaler? (Yes) No

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? (Yes) No



Date of photograph 3/17/21

Applicant's initial AB

STATE OF Nevada
ss.
COUNTY OF Lincoln

I, Andrew Bleak, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Andrew Bleak
Original Signature of Applicant

Subscribed and Sworn to before me this 17th day of March, 2021.
by Andrew Bleak.
Betsy Comella
Notary Public

BETSY COMELLA
Notary Public, State of Nevada
Appointment No. 16-4059-11
My Appt. Expires Nov 24, 2024
(seal)

Applicant's initial AB

ADDITIONAL INFORMATION

See attached papers

Applicant's initial AB AB

Pharmacy Application Continuance

3. A. Kenlsey Bleak [redacted] Omaha, NE [redacted] South 4th St. Panaca, NV

Joel Bleak Show Low, AZ South 4th St. Panaca, NV

Jane Bleak St. George, UT South 4th St. Panaca, NV

Ivy Bleak St. George, UT South 4th St. Panaca, NV

Eve Bleak St. George, UT South 4th St. Panaca, NV

3. D.

Aaron Bleak [redacted] W. 1220 S. Riverton, UT Architect

Elizabeth Reber [redacted] Homemaker

Jason Bleak [redacted] Blue Ridge Rd. Battlemountain, NV Hospital Admin.

Judy Leavitt [redacted] Homemaker

Robin Bleak [redacted] N. 2nd St. Panaca, NV Homemaker

Tyler Heaton [redacted] High School Teacher/Phamacy co-owner

Nelson Collin Bleak [redacted] Lilith Ave Pioche, NV Highway Patrol Officer

Ina Marie Edgar [redacted] Elementary School Parapro

Jeffrey Bleak [redacted] Snapdragon Ladera Ranch, CA Construction

Nathan Bleak [redacted] Devens Dr. Brentwood, TN Healthcare Admin.

Zoe Clement [redacted] Advertising

6. C.

I was questioned regarding a bombing that was a block away from my house by state investigators.

I was questioned by pharmacy investigators regarding Meadow Valley Pharmacy fraud.

AB
AB

7.

12/2011-8/2013	163 N. 2nd W. Snowflake, AZ 85937
8/2013-10/2013	14 S. 275 W. Enterprise, UT 84937
10/2013-7/2014	135 S. 4th St. Panaca, NV 89042
7/2014- Present	[redacted] South 4th St. Panaca, NV 89042

15-17.

Meadow Valley Pharmacy's license was surrendered and the owner, Adam Katschke, plead guilty to charges dealing with fraudulent billing.

AB

AB

5

MATRIX GUIDELINE FOR DISCIPLINARY ACTIONS

	1st Action	2nd Action	3rd Action
Non ingested error	Letter	Letter	Hearing
No counseling	$750.00	Counseling CE + $1000.00	Hearing
Attorney Fees and Costs	Actual	Actual	Actual
Ingested no potential harm	$500.00	$1000.00	Hearing
Ingested with potential harm or adverse outcomes	$1000.00	Hearing	Hearing
Ingested with negative outcome or patient discomfort. No institution intervention	Hearing	Hearing	Hearing
Ingested with significant negative health circumstance. With institution admit	Hearing	Hearing	Hearing
Ingested with death related to inappropriate drug therapy	Hearing	Hearing	Hearing

The investigative committee will review each case individually and may recommend a board hearing, particularly with mitigating circumstances such as inappropriate technician involvement or pharmacist malfeasance.

In certain cases with ingested errors and significant negative health circumstances requiring institutional care, the investigative committee recommendation will be a board hearing.

In all death cases resulting from inappropriate drug therapy a board hearing will occur.

Attorney fees and costs may be added in contested disciplinary actions requiring extensive attorney preparation and presentation and are not described in the above matrix.

The board has directed that ownership may be charged in disciplinary cases. In non-ingested errors copies of admonition letters will be sent to management. Accumulative actions for ownership monitoring will be based upon a 3 year period. All actions including non-ingested errors will be given a case number and monitored.

The Board has the authority to fine from $0.00 to $10,000 for each Cause of Action.

Updated May 2019

ANNUAL DISCIPLINE CASES Reporting Period: January 2021 – June 2021			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
RW allowed other individuals to use his credentials to write and authorize prescriptions while he was out of the country.	N/A	CS registration is revoked; the revocation is stayed; CS registration is placed on probation for two years. RW shall pay a $5,000 fine and $2,000 for recoverable attorney's fees and costs.	N/A
DS, JM, and DB surrendered their DEA registrations for cause. Respondents no longer authorized by Federal or State law to prescribe or otherwise dispense a controlled substance.	N/A	Revoked	N/A
JP dispensed dangerous drugs for Nevada patients without a valid dispensing practitioner registration, from May 2017 until March 2020.	N/A	JP complied with a March 2020 cease and desist and citation order including payment of a $5,000 administrative fine. JP shall pay $950.00 for recoverable attorney's costs and fees.	N/A
KM allowed non-practitioner/non-licensed staff to possess, prescribe, obtain, access, and store dangerous drugs and/or administer drugs when he was not on site at the facility, before he examined the patient and before he wrote a patient-specific order; purchased sterile compounded dangerous drugs from an outsourcing facility not licensed with the Board. KM voluntarily placed his license from the NSBME to practice medicine on inactive status; KM's CS registration placed on inactive status.	N/A	KM's CS registration shall remain inactive until he petitions the Board for reinstatement and presents proof that his license to practice medicine from the NSBME is active and in good standing. KM shall pay a $1,500 fine and $1,000 in attorney's fees and costs.	N/A
ES's license to practice dentistry was revoked by the NSBDE for numerous violations of NRS Chapter 631. The NVBOP served ES with notice that the revocation of her NSBDE license operated as an immediate	N/A	Revoked	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January 2021 – June 2021			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
suspension of her Nevada Controlled Substance Certificate of Registration. Respondent is no longer authorized by Federal or State law to prescribe or otherwise dispense a controlled substance.			
MG's voluntarily surrender of his controlled substance and practitioner dispensing registrations constitute disciplinary action.	N/A	MG may not prescribe controlled substances or dangerous drugs until he applies to the Board for issuance of a controlled substance and/or practitioner dispensing registration. He shall pay a $3,217.50 attorney's fees and costs.	N/A
CF's license to practice medicine was placed on inactive status by the NSBME. CF is no longer authorized by Federal or State law to prescribe or otherwise dispense a controlled substance.	N/A	CF's controlled substance registration shall remain inactive until such time he petitions the Board for reinstatement and presents proof that his license to practice medicine from the NSBME is active and in good standing.	N/A
RPH DN diverted dangerous drugs for his personal use and furnished some of the diverted drugs to at least one other person.	N/A	DN's pharmacist certificate of registration is revoked. He shall pay a fine of $5,000 and $1,300 in attorney's costs and fees.	N/A
EM surrendered his DEA registration for cause. EM no longer authorized by Federal or State law to prescribe or otherwise dispense a controlled substance.	NA	Revoked for a period of 5 years; fined $5,000 and $812.50 for attorney's fees and costs.	N/A
RP allowed non-practitioner/non-licensed staff to possess or prescribe dangerous drugs to patients	N/A	Fined $2,000, $1,500 for attorney's fees and costs, and establish new policies and procedures.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January 2021 – June 2021			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
and allowed non-licensed staff to obtain, access, possess and store dangerous drugs and/or administer drugs with whom RP had not established a bona fide therapeutic relationship and for whom RP had neither diagnosed or determined a dangerous drug was medically necessary.			
EM: The NSBME imposed discipline on EM's License No. PA1209 to practice medicine for violations of NRS Chapter 630 related to prescribing opioid medication.	N/A	EM's CS registration is suspended; the suspension is stayed and EM is placed on probation for a period of one year. EM fined $2,500; $1,000 attorney's fees and costs, and establish policies and procedures to ensure that any controlled substance prescription complies with all applicable regulations.	N/A
IF: NSBME entered an order in Case No. 20-38677, and imposed discipline on IF's License No. 14038 to practice medicine for violations of NRS Chapter 630 related to failure to adequately supervise a physician assistant prescribing opioid medication.	N/A	IF fined $2,500; $1,000 in attorney's fees and costs; and establish policies and procedures to ensure any controlled substance prescription issued for the treatment of chronic pain complies with all applicable regulations.	N/A
PK: The Florida State Board of Medical Examiners entered an order in Case No. 20-1903-552, and PK's License No. ME0093253 to practice medicine in Florida was suspended on the basis that Respondent "is unable to practice medicine with	N/A	Revoked. PK may not petition for reinstatement of his certificate or registration for a period of 1 year.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January 2021 – June 2021			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
reasonable skill and safety." On November 17, 2020, PK requested that his License No. 14422 from the Nevada State Board of Medical Examiners be placed on inactive status. PK surrendered his DEA Certificate of Registration No. FK5849419 for cause on November 19, 2020.			
FS: NSBMW entered an order in Case No. 20-4041-1 and imposed discipline on FS's License No. 2641 to practice medicine for violations of NRS 630.306(1)(r) and NRS 630.306(1)(b)(3). FS failed to put into practice policies and procedures to ensure that dangerous drugs (cosmetic injectables) were purchased, accessed, stored, possessed, administered, furnished and/or dispensed to patients in compliance with NRS 454.213(1), NRS 454.221 and/or NRS 454.316.	N/A	Fined $3,000; $1,000 attorney's fees and costs; establish policies and procedures.	N/A
GM: In April 14, 2021, the Board entered an Order pursuant to stipulation with GM. On April 21, 2021, GM surrendered his DEA Certificate of Registration No. MM2157647 for cause.	N/A	Revoked. GM may not petition for reinstatement of his certificate or registration for a period of 1 year.	
VM: On July 22, 2020, the DEA issued an Order to Show Cause and Immediate Suspension of Respondent's DEA Certificate of Registration No. BM7876800 pursuant to 21 U.S.C. § 824(d). VM regularly prescribed controlled substances to patients outside of the usual course of the professional practice of		Revoked. VM may not petition for reinstatement of his certificate or registration for a period of 2 years; fined $10,000; $1,989.10 attorneys costs and fees.	

ANNUAL DISCIPLINE CASES Reporting Period: January 2021 – June 2021			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
medicine in Nevada in violation of 21 U.S.C. § 823(f)(2), 21 CRF § 1306.04(a) and NRS 453.38, and failed to comply with applicable federal and state laws relating to controlled substances, in violation of 21 U.S.C § 823(f)(4). VM possessed and/or dispensed controlled substances in violation of the DEA Suspension for Cause and corresponding suspension of Certificate of Registration No. CS11174.			

5A

FILED
MAY 28 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURORA BEJTO, RPH,** **Certificate of Registration No. 18384,** **Respondent.**	**CASE NO. 21-021-RPH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent, Aurora Bejto, R.Ph., Certificate of Registration No. 18384, was a pharmacist registered by the Board.

FACTUAL ALLEGATIONS

2. Respondent was employed as a pharmacist at both Omnicare of Nevada (Omnicare), located at 9475 Double R Boulevard - Suite 8, Reno, and at several Northern Nevada Raley's pharmacies at the time of the events alleged herein.

3. Omnicare and Raley's submitted DEA Form 106 documentation to the Board reporting the theft of controlled substances in December 2020 and January 2021. The subsequent investigation produced evidence that Respondent diverted the following controlled substances for her personal use:

Omnicare of Nevada [9475 Double R Boulevard - Suite 8, Reno]
43 tablets - 7.5 mg/325 mg Hydrocodone-Acetaminophen
28 tablets - 5 mg/325 mg Hydrocodone-Acetaminophen
20 tablets - 10 mg/325 mg Hydrocodone-Acetaminophen
10 tablets - 5 mg/325 mg Hydrocodone-Acetaminophen
Time period of theft (or first discovery): 12/6/2020 to 12/20/2020

Raley's Pharmacy #105 [1630 Robb Drive, Reno]
99 tablets - 10 mg Zolpidem
101 tablets - 1 mg Alprazolam
Raley's Pharmacy #109 [1363 Hwy. 395 North, Gardnerville]
89 tablets - 10 mg Zolpidem
Raley's Pharmacy #115 [1075 North Hills Boulevard, Reno]
389 tablets - 10 mg Zolpidem
Raley's Pharmacy #122 [1400 State Route 95A, Fernley]
281 tablets - 10 mg Zolpidem
Time period of theft (or first discovery): 1/11/2021 to 2/23/2021

4. On or about February 22, 2021, Board staff contacted Respondent as she reported for work at the Post-Acute Medical Pharmacy in Sparks, at which time she denied working at Omnicare in December 2020, and denied diverting controlled substances from the pharmacy. That afternoon, Respondent was interviewed at the Board office with counsel present; during the course of the interview, she admitted that she began stealing Ambien from Omnicare pharmacy while conducting inventory in October 2020, that she diverted Hydrocodone-Acetaminophen on one occasion only while conducting inventory in November 2020, and that she diverted Ambien on one occasion from Raley's Pharmacy #106 located at 701 Keystone Avenue, Reno, in December 2020. Respondent denied any other thefts of controlled substances.

5. On or about March 10, 2021, Respondent signed a written admission to diverting Ambien from Raley's sometime in September or October 2019, diverting Hydrocodone-Acetaminophen from Omnicare of Nevada during the week of October 19, 2020, and diverting Ambien from Omnicare of Nevada on or about December 6, 2020.

APPLICABLE LAW

6. It is a felony offense to acquire a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 846; NRS 453.331(1)(d); NRS 453.391(1).

7. It is a felony offense to possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 844; 21 U.S.C. § 846; NRS 453.336(1); NRS 453.381(8).

8. It is a criminal offense to use a controlled substance except as authorized by law. 42 U.S.C. § 12210; NRS 453.411(1).

9. Willfully making a materially false statement in the course of a Board investigation is a criminal offense and grounds for suspension or revocation of any license or registration issued by the Board. NRS 197.190; NRS 639.210(9).

10. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. It is grounds for suspension or revocation of any license or registration issued by the Board to willfully make to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of NRS Chapter 639. NRS 639.210(9

13. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

14. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

FIRST CAUSE OF ACTION
Unlawful Acquisition of Controlled Substances

15. By diverting and acquiring controlled substances as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 846, NRS 453.331(1)(d) and/or NRS 453.391(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

SECOND CAUSE OF ACTION
Unlawful Possession of Controlled Substances

16. By diverting and possessing controlled substances as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 841(a), 21 U.S.C. § 844, 21 U.S.C. § 846, NRS 453.336(1), NRS 453.381(8) and/or NRS 454.316(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

THIRD CAUSE OF ACTION
Unlawful Use of Controlled Substances

17. By diverting and using controlled substances as alleged herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 42 U.S.C. § 12210 and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

FOURTH CAUSE OF ACTION
Unprofessional Conduct - Diversion

18. By diverting controlled substances as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

FIFTH CAUSE OF ACTION
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

19. By diverting controlled substances as alleged herein, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct

contrary to the public interest pursuant to NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

SIXTH CAUSE OF ACTION
False Statements in Course of Investigation

20. By willfully making false statements in the course of the Board's investigation, as alleged herein, that are material to the administration and enforcement of law, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 197.190, and is subject to discipline pursuant to NRS 639.210(9).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 18th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURORA BEJTO, RPH,** **Certificate of Registration No. 18384,** **Respondent.**	**CASE NOS. 21-021-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURORA BEJTO, RPH,** **Certificate of Registration No. 18384,** **Respondent.**	**CASE NO. 21-021-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

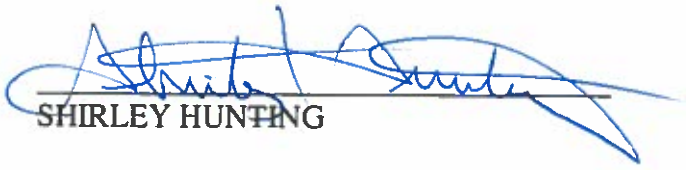
_____

AURORA BEJTO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Aurora Bejto, R.Ph.
715 James Ct.
Reno, NV 89503



SHIRLEY HUNTING

Stipulation of Findings of Fact
Aurora Bejto

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Aurora Bejto ("Respondent") and this matter, because at all relevant dates and times referenced in this Stipulation, the Respondent was registered by the Board as a pharmacist in the State of Nevada. Certificate of Registration No. 18384.

2. The Respondent was working per diem as a pharmacist for various pharmacies on the dates and times of the events referenced in this Stipulation.

3. Respondent has been informed that the Board is investigating allegations of Respondent's diverting controlled substances from pharmacies at which Respondent worked. Respondent understands that the Board's investigation is ongoing.

4. On or about February 22, 2021, Respondent admitted to Board staff that Respondent had had diverted certain controlled substances from her places of employment.

5. During 2019 and 2020 and before, Respondent had valid prescriptions for Hydrocodone-Acetamin ("Norco") and for Tramadol to treat neck pain that was the result of an automobile accident in 2015. During the same period, Respondent had valid prescriptions for Zolpidem Tartrate ("Ambien") to address sleep issues.

6. Respondent admits that over time Respondent became addicted to Ambien, and developed a tolerance to Norco that caused her to increase her dosage of Norco and other pain medications. She attempted to stop or decrease her use of these drugs without professional help, but was unsuccessful.

7. Despite having valid prescriptions for Norco, Tramadol, and Ambien, Respondent admits that she did divert Norco and Ambien.

8. In particular, at the end of a shift at Omnicare on or about the week of October 19, 25, 2020, Respondent noted that the inventory showed that there were 10 tablets too many of Norco in the pharmacy. Respondent diverted for her own use the "extra" tablets of Norco.

9. Respondent also recalls diverting 4-5 tablets of Ambien from Railey's in September or October of 2019 for her own use.

10. Respondent recalls diverting an open bottle of Ambien from Omnicare containing about 60 pills or so for her own use. Based on the statements of Board staff and her work schedule, Respondent believes this diversion occurred on or about December 6,

2020. This information as to the December 6, 2020 date was given to the Respondent on or about February 22, 2020.

10. On or about February 23, 2020, Respondent contacted Carol Schaye, RNc, LADC at Carols Counseling to have an assessment performed and to make arrangements for counseling, treatment and testing, which she has continued with since that date. Counseling has involved group and one-on-one Zoom sessions. Respondent has also attended five Narcotics Anonymous meetings and has had two clean urine screens.

11. Having failed in the past to stop using Norco and Ambien on her own, Respondent intends to address her addiction issues under the guidance of a professional counselor until the counselor advises her otherwise.

Date: March 10, 2021.

Aurora Bejto

Aurora Bejto, RPh

5B

FILED
JUN 02 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

DIRECT COMPOUNDING AND OUTSOURCING, LLC, Pharmacy License No. PH04006,

SCOT SILBER, RPH, Certificate of Registration No. 08362,

MICHAEL THOMAS, PT Certificate of Registration No. PT05905,

KRYSTAL HERNANDEZ, PT Certificate of Registration No. PT10671,

Respondents.

CASE NO. 19-070-PH-S
19-070-RPH-S
19-070-PT-A-S
19-070-PT-B-S

AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, R.Ph., in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both an amended notice of intended action under NRS 233B.127(3) and as an amended accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Direct Compounding and Outsourcing, LLC ("Direct") held a Nevada Pharmacy License No. PH04006; Respondent Scot Silber ("Silber") held a Nevada Pharmacist Certificate of Registration No. 08362; Respondent Michael Thomas ("Thomas") held a Nevada Pharmaceutical Technician Registration No. PT05905; and Krystal Hernandez ("Hernandez") held a Nevada Pharmaceutical Technician Registration No. PT10671, all issued by the Board.

DISCIPLINARY HISTORY

2. In April 2004, the Board entered an Order in *Board of Pharmacy v. Respondent Scot M. Silber, R.Ph., Case No. 03-016-RPH-S,* for violations resulting in the mislabeling of dosage directions on a prescription label for Roxanol Liquid, a Schedule II opioid analgesic. The patient ingested an unknown quantity of the medication and was subsequently hospitalized. The Board ordered Silber to pay a fine of $500.00.

3. In October 2012, the Board entered a Stipulation and Order in *Board of Pharmacy v. Respondent Scot M. Silber, R.Ph., Case No. 11-090-RPH-S,* for violations resulting in a dispensing error. Silber misread a prescription and compounded 20 mg/cc morphine sulfate with ***2,500 mcg/cc baclofen*** rather than the 20 mg/cc morphine sulfate with ***250.0 mcg/cc baclofen*** as prescribed. The compound was administered to the patient who was subsequently hospitalized for baclofen toxicity. The Board placed Silber on probation for two years and imposed a $2,500 fine.

FACTUAL ALLEGATIONS

4. Respondent Direct is located on 1850 Whitney Mesa Boulevard, #180, Henderson, Nevada 89014. On April 4, 2019, pharmacist T.B., was terminated as managing pharmacist of Direct. Direct did not timely notify the Board about the change in managing pharmacist.

5. Respondent Silber was hired as the managing pharmacist of Direct beginning on or about April 22, 2019. However, on or about April 18, 2019, Respondent Silber supervised and signed off as the pharmacist for Respondent Direct on one 100 batch yield of Oxandrolone 25 mg capsule, and one 30 batch yield of Testosterone Cypionate (6 ml vial) 200 mg/ml injectable.

6. Respondents Thomas and Hernandez were employed by Direct during the times alleged.

7. On or about April 4, 2019, Thomas was contacted by Ellie Gerber ("Gerber"), one of the managing members/owners of Direct, to meet the locksmith at Direct to re-key the

pharmacy door. Thomas was given three (3) sets of keys to Direct's pharmacy by the locksmith. Hernandez received a key to Direct on April 8, 2019.

8. Between April 4 and April 22, 2019, Thomas and/or Hernandez had unauthorized access to Direct's controlled substances and dangerous drugs inventory without a pharmacist present.

APPLICABLE LAW

9. Each pharmacy must be managed by a registered pharmacist in compliance with NRS 639.220. Failure to place a registered pharmacist in charge of a pharmacy is a criminal offense. NRS 639.284.

10. The security of a pharmacy premises and inventory must be maintained in conformance with federal and state law. NAC 639.470; NAC 639.520; 21 CFR § 1301.71.

11. A managing pharmacist is responsible for violations committed by the pharmacy's employees. NRS 639.220(1); NAC 639.702.

12. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230(5); NAC 639.702; NAC 639.945(2).

13. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. The Board may suspend or revoke a license or registration pursuant to NRS 639.210(11) if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs.

15. The Board may suspend or revoke a license or registration pursuant to NRS 639.210(12) if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy.

16. The Board may suspend or revoke a license or registration pursuant to NRS 639.210(15) when a person has "as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of this chapter or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision."

FIRST CAUSE OF ACTION
Violations of Law and Unprofessional Conduct
(Respondent Silber)

17. As a registered pharmacist and/or supervising pharmacist acting on behalf of Direct on or about April 18, 2019, Silber knew or should have known that Thomas and Hernandez were unlawfully accessing Direct's premises, including the pharmacy, and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.220(1), NAC 639.470, NAC 639.520, NAC 639.702, and/or 21 CFR § 1301.71, performed his duties in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210(4), (11), (12), (15), and/or NRS 639.255.

SECOND CAUSE OF ACTION
Violations of Law and Unprofessional Conduct
(Respondents Thomas and Hernandez)

18. By knowingly accessing Direct's premises without a pharmacist present, Thomas and Hernandez violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.520, performed their duties as pharmaceutical technicians in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and are therefore subject to discipline pursuant to NRS 639.210(4) and (12), and/or NRS 639.255.

///

///

///

THIRD CAUSE OF ACTION
Failure to Place Managing Pharmacist in Charge
(Respondent Direct)

19. By failing to place a managing pharmacist in charge of the pharmacy April 4 and April 22, 2019, and failing to timely notify the Board of a change in managing pharmacists, Direct violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.220 and/or NRS 639.284(1), and is subject to discipline pursuant to NRS 639.210(12), and/or NRS 639.255.

FOURTH CAUSE OF ACTION
Failure to Maintain Security of the Pharmacy Premises
(Respondent Direct)

20. By failing to maintain the security of the pharmacy premises and inventory and granting unlawful access to Thomas and Hernandez to Direct, Direct violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.470, NAC 639.520, and/or 21 CFR § 1301.71, and is subject to discipline pursuant to NRS 639.210(11) and (12), and/or NRS 639.255.

FIFTH CAUSE OF ACTION
Pharmacy/Owner Responsibilities
(Respondent Direct)

21. As the owners/operators of Direct at the time of each of the violations alleged herein, Direct is responsible for the violations, including those of its employees, pursuant to NRS 639.230(5), NAC 639.702, and/or NAC 639.945(2), and is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license/registration of these Respondents.

Signed this 2nd day of June, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board, and to submit an answer the Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, then the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DIRECT COMPOUNDING AND OUTSOURCING, LLC,** **Pharmacy License No. PH04006,** **Respondent.**	**CASE NO. 19-070-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of June, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Direct Compounding
1850 Whitney Mesa Blvd. #180
Henderson, NV 89014

SHIRLEY HUNTING

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

James D. Boyle, Esq.
400 S. 4th Street, Suite 300
Las Vegas NV 89101

James D. Boyle, Esq.
800 S. Meadows Pkwy., Suite 800
Reno, NV 89521

Scot Silber, R.Ph.
3155 Hazy Hills Ave.
Henderson, NV 89052

Michael Thomas, PT
4260 NEWCASTLE RD
LAS VEGAS, NV, 89103

Krystal Hernandez, PT
9160 Whatley St.
Las Vegas,NV, 89148

Direct Compounding
1850 Whitney Mesa Blvd. #180
Henderson, NV 89014

SHIRLEY HUNTING

FILED 1312
JUN 24 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DIRECT COMPOUNDING AND OUTSOURCING, LLC Pharmacy License No. PH04006, SCOT SILBER, RPH, Certificate of Registration No. 08362, MICHAEL THOMAS, PT Certificate of Registration No. PT05905, KRYSTAL HERNANDEZ, PT Certificate of Registration No. PT10671, Respondents.	CASE NOS. 19-070-PH-S 19-070-RPH-S 19-070-PT-A-S 19-070-PT-B-S **ANSWER AND NOTICE OF DEFENSE TO AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

Pursuant to NRS § 639.244, Respondents Direct Compounding and Outsourcing, LLC ("Direct Compounding") and Scot M. Silber, R.Ph. ("Mr. Silber") (together, "Respondents"),[1] hereby respond as follows to the allegations contained in Petitioner's Amended Notice of Intended Action and Accusation dated June 2, 2021 and served on Respondents on or about June 9, 2021 (the "Amended Accusation"). Respondents submit this Answer and Notice of Defense to Amended Notice of Intended Action and Accusation (the "Answer") in supplementation to the following: (1) Statement of Ellie Gerber ("Ms. Gerber") dated April 24, 2019; (2) Statement of Scot Silber dated April 22, 2019; (3) Statement of Michael Thomas of similar date; and (4) Statement of Krystal Hernandez dated April 23, 2019.

[1] Counsel for Respondents does not independently represent either Respondents Michael Thomas ("Mr. Thomas") or Krystal Hernandez ("Ms. Hernandez"). Counsel is prepared, however, to address the allegations of the Amended Accusation as made against both Mr. Thomas and Ms. Hernandez in the context of their respective employment with Direct Compounding during the timeframes relevant to the Amended Accusation.

This Answer is based upon the pleadings and records on file in this matter, the Answer, Affirmative Defenses and Mitigating Circumstances set forth below, the Declaration of Ellie Gerber attached hereto and incorporated herein by this reference as Exhibit A, the Declaration of Scot M. Silber, R.Ph. attached hereto and incorporated herein by this reference as Exhibit B, and the presentation and evidence made to the Board pursuant to NRS §§ 233B.121 – 233B.127 and other operation of law.

A hearing on the Amended Accusation is presently set before the Nevada State Board of Pharmacy (the "Board") on July 14, 2021.

ANSWER

A. Statement of Completeness and Clarity

Respondents have no objection to the Amended Accusation as being incomplete or failing to state clearly the charges against Respondents.

B. Response to Allegations

Respondents, for and as their Answer to the Amended Accusation, admit, deny and allege as follows:

I. RESPONDENTS' RESPONSE TO THE BOARD STAFF'S ALLEGATIONS

JURISDICTION

1. Respondents admit that the Board has jurisdiction over this matter, and further admit that the Board's allegations regarding Direct Compounding's Nevada Pharmacy License No. and Mr. Silber's Nevada Pharmacist Certificate of Registration No. are accurate. To the best of Respondents' knowledge, the Board's allegations regarding the Pharmaceutical Technician Registration Nos. for Mr. Thomas and Ms. Hernandez are also accurate.

///

///

DISCIPLINARY HISTORY

2. Mr. Silber admits the general factual recitation set forth in Paragraph 2 of the Amended Accusation, but further states that the referenced Board Order of April 2004 speaks for itself. Mr. Silber further asserts that he timely complied with and satisfied the Board's imposition of the referenced fine. Direct Compounding is without sufficient knowledge to know the truth or falsity of the allegations of Paragraph 2 of the Amended Accusation as the referenced facts predate Direct Compounding's formation date (June 12, 2017).

3. Mr. Silber admits the general factual recitation set forth in Paragraph 3 of the Amended Accusation, but further states that the referenced Board Stipulation and Order of October 2012 speaks for itself. Mr. Silber further asserts that he timely complied with and satisfied the Board's imposition of the referenced probation and fine. Direct Compounding is without sufficient knowledge to know the truth or falsity of the allegations of Paragraph 3 of the Amended Accusation as the referenced facts predate Direct Compounding's formation date (June 12, 2017).

FACTUAL ALLEGATIONS

4. Respondents admit that Direct Compounding is located at the referenced address. Direct Compounding further admits that pharmacist T.B. was terminated on or about April 4, 2019. Direct Compounding disputes that it did not notify the Board regarding the termination of pharmacist T.B., as explained in Affirmative Defense and Mitigating Circumstances Nos. 16 and 17. Mr. Silber is without sufficient knowledge to know the truth or falsity of the allegations of Paragraph 4 of the Amended Accusation, and therefore denies the same.

5. Respondents admit that Mr. Silber was hired as the managing pharmacist for Direct Compounding beginning on or about April 22, 2019, as alleged in Paragraph 5 of the Amended Accusation. Respondents acknowledge that Mr. Silber supervised and signed off as the

pharmacist for Direct Compounding on one 100 batch yield of Oxandrolone 25 mg capsule, and one 30 batch yield of Testosterone Cypionate (6 ml vial) 200 mg/ml injectable, as further alleged in Paragraph 5 of the Amended Accusation, as explained in Affirmative Defense and Mitigating Circumstances Nos. 10 and 25.

6. Respondents admit Paragraph 6 of the Amended Accusation.

7. Direct Compounding disputes that Ellie Gerber ("Ms. Gerber") contacted Mr. Thomas on or about April 4, 2019, about meeting a locksmith at the offices of Direct Compounding; nevertheless, Direct Compounding admits that, on or about the referenced dates, Mr. Thomas was so-requested to meet a locksmith at the offices of Direct Compounding. Direct Compounding further admits that Mr. Thomas received three (3) sets of keys to the offices of Direct Compounding from said locksmith, and that Ms. Hernandez received one (1) set of said keys from Mr. Thomas on or about April 8, 2019. Mr. Silber is without sufficient knowledge to know the truth or falsity of the allegations of Paragraph 7 of the Amended Accusation, and therefore denies the same.

8. Direct Compounding disputes the allegations of Paragraph 8 of the Amended Accusation as explained in Affirmative Defense and Mitigating Circumstances Nos. 10, 12, 13, 14, 15, 18, 19, 21, and 25. Direct Compounding admits that, during certain dates within the April 4 – 22, 2019 timeframe, Mr. Thomas and/or Ms. Hernandez were able to access Direct Compounding's offices when a pharmacist was not present, and that such access included the potential for access to Direct Compounding's minimal inventory of a single controlled substance (testosterone). Mr. Silber is generally without sufficient knowledge to know the truth or falsity of the allegations of Paragraph 8 of the Amended Accusation, and therefore denies the same as further explained in Affirmative Defense and Mitigating Circumstances Nos. 10, 21, and 25.

APPLICABLE LAW

9. Respondents state that Paragraph 9 of the Amended Accusation sets forth an accurate summation of the legal requirements of NRS §§ 639.220 and 639.284, but said paragraph does not set forth the complete language of either statute. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation of NRS § 639.220 and/or NRS § 639.284.

10. Respondents state that Paragraph 10 of the Amended Accusation sets forth a general summation of the legal requirements of certain provisions of NRS § 639.470, NAC § 639.520, and 21 CFR § 1301.71, but said paragraph does not set forth the complete language of either the statute or the regulatory provisions. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation of NRS § 639.470, NAC § 639.520, and/or 21 CFR § 1301.71.

11. Respondents state that Paragraph 11 of the Amended Accusation sets forth a general summation of the legal requirements of NRS § 639.220(1) and NAC § 639.702, but said paragraph does not set forth the complete language of either the statute or the regulatory provision. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation of NRS § 639.220(1) and/or NAC § 639.702.

12. Respondents state that Paragraph 12 of the Amended Accusation sets forth an accurate summation of the legal requirements of and NAC §§ 639.702 and 639.945(2), but said paragraph does not set forth the complete language of either regulatory provision. Respondents further state that NRS § 639.220(5) does not stand for the legal requirement alleged in Paragraph 12 of the Amended Accusation, as this statute is a remedial provision. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation of NRS § 639.630(5), and/or of NAC §§ 639.702 or 639.945(2).

13. Respondents state that Paragraph 13 of the Amended Accusation sets forth an accurate summation of the legal requirements of NRS § 639.210(4) and NAC § 639.945(1)(i), but said paragraph does not set forth the complete language of either the statute or the regulatory provision. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation of NRS § 639.210(4) and/or NAC § 639.945(1)(i).

14. Respondents state that Paragraph 14 of the Amended Accusation sets forth an accurate summation of the remedial allowances of NRS § 639.210(11), but said paragraph does not set forth the complete language of the statute. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation for which the remedial allowances of NRS § 639.210(11) are applicable.

15. Respondents state that Paragraph 15 of the Amended Accusation sets forth an accurate summation of the remedial allowances of NRS § 639.210(12), but said paragraph does not set forth the complete language of the statute. Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation for which the remedial allowances of NRS § 639.210(12) are applicable.

16. Respondents state that Paragraph 16 of the Amended Accusation sets forth an accurate recitation of the remedial allowances of NRS § 639.210(15). Respondents do not admit that Direct Compounding, Mr. Silber, Mr. Thomas and/or Ms. Hernandez committed a violation for which the remedial allowances of NRS § 639.210(15) are applicable.

FIRST CAUSE OF ACTION
Violations of Law and Unprofessional Conduct
(Respondent Silber)

17. Respondent Silber disputes the allegations of Paragraph 17 of the Amended Accusation, as explained in Affirmative Defenses and Mitigating Circumstances Nos. 10, 21, and 25.

SECOND CAUSE OF ACTION
Violation of Law and Unprofessional Conduct
(Respondents Thomas and Hernandez)

18. Respondents deny the allegations of Paragraph 18 of the Amended Accusation, to the extent that these allegations are applicable in any manner to either Direct Compounding and/or Mr. Silber.

THIRD CAUSE OF ACTION
Failure to Place Managing Pharmacist In Charge
(Respondent Direct)

19. Direct Compounding admits the factual allegations set forth in Paragraph 19 of the Amended Accusation, but denies the legal allegations of said paragraph as explained in Affirmative Defenses and Mitigating Circumstances Nos. 5, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 21, 23, 24, 25, and 26.

FOURTH CAUSE OF ACTION
Failure to Maintain Security of Pharmacy Premises
(Respondent Direct)

20. Direct Compounding denies the allegations of Paragraph 20 of the Amended Accusation, as explained in Affirmative Defenses and Mitigating Circumstances Nos. 5, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 23, 24, 25, and 26.

FIFTH CAUSE OF ACTION
Pharmacy/Owner Responsibilities
(Respondent Direct)

21. Direct Compounding admits the factual allegations set forth in Paragraph 21 of the Amended Accusation, but denies the legal allegations of said paragraph as explained in Affirmative Defenses and Mitigating Circumstances Nos. 5, 6, 8, 9, 10, 11, 12, 13, 15, 16, 17, 18, 19, 23, 24, and 26.

///

///

AFFIRMATIVE DEFENSES AND MITIGATING CIRCUMSTANCES

1. Respondents hereby assert the affirmative defenses of estoppel, laches, acquiescence, waiver, and applicable statutes of limitation.

2. Pursuant to NRS § 233B.123, Respondents object to the allegations set forth in Paragraphs 2 and 3 of the Amended Accusation as being irrelevant and immaterial to this matter, and as being presented in derogation of NRS §§ 48.025, 48.035, and 48.045.

Background Regarding Direct Compounding and Scot M. Silber, R.Ph.

3. Direct Compounding was incorporated on June 12, 2017. Since August 30, 2019, Direct Compounding has been owned and operated by Ellie Gerber ("Ms. Gerber") and Alicia Smith ("Ms. Smith"). Ms. Gerber and Ms. Smith are residents of California.

4. At the time of incorporating Direct Compounding and throughout the relevant timeframe of the Amended Accusation, both Ms. Gerber and Ms. Smith were novice owners of a pharmacy and were, in full candor to the Board, undereducated with regard to state and federal statutory and regulatory obligations applicable to owners of a licensed and registered pharmacy. Respondents respectfully suggest that the events addressed in the Amended Accusation are a byproduct of this novice experience, but that the success of both Ms. Gerber and Ms. Smith—and, by extension, of Direct Compounding as well—in gaining competency in operating a licensed pharmacy, is best evidenced through the complete absence of investigatory or disciplinary issues with state and federal authorities subsequent to the events addressed in the Amended Accusation.

5. Direct Compounding initially hired Pharmacist T.B. as its Pharmacist-in-Charge ("PIC"). Direct Compounding employed Pharmacist T.B. as its PIC from June 12, 2017 through approximately April 4, 2019. Due to their inexperience in the ownership of a pharmacy, Ms. Gerber and Ms. Smith placed full faith and responsibility in Pharmacist T.B. to oversee, operate,

manage, and supervise Direct Compounding, and further to ensure Direct Compounding was compliant with all statutory and regulatory obligations.

6. For the time period of June 2017 through April 2019, Direct Compounding did not receive any disciplinary notifications or legal actions from either the Board or the United States Food and Drug Administration (the "FDA"), or from any other state or federal agencies or oversight personnel. Neither has Direct Compounding received any disciplinary notifications or other legal actions from the Board or the FDA, or from any other state or federal agencies or oversight personnel, since April 2019. The Board did not seek (and has not sought) to make any emergency or summary suspension of Direct Compounding's license or of any registrations held by Mr. Silber, Mr. Thomas, or Ms. Hernandez related to the allegations of the Amended Accusation, as is permissible under NRS § 233B.127(3). Furthermore, Direct Compounding has complied with all recommendations by Board Staff and federal agencies pursuant to regulatory inspections.

7. Direct Compounding hired Mr. Thomas on November 9, 2018 and he was employed through October 22, 2020. Direct Compounding hired Ms. Hernandez on July 17, 2018 and she was employed through June 4, 2020. Neither Mr. Thomas nor Ms. Hernandez is presently employed with Direct Compounding.

8. On or about April 4, 2019, Direct Compounding terminated Pharmacist T.B., based upon multiple issues which required an immediate separation of Pharmacist T.B. from employment with Direct Compounding.

9. Immediately thereafter, Direct Compounding began its search for a new PIC to replace Pharmacist T.B.

10. On or about April 15, 2019, Ms. Gerber met with Mr. Silber at the business location of Direct Compounding, for the purposes of interviewing Mr. Silber for the position of PIC. Direct Compounding offered Mr. Silber the position of PIC on or about April 16, 2019. Mr. Silber accepted this position, with an official payroll start date of April 22, 2019 but an actual onsite start date of April 15, 2019. Mr. Silber resigned his position as PIC for Direct Compounding effective June 1, 2021.

Factual Points Relevant to the Amended Accusation

11. Direct Compounding recognizes that it failed to notify Board Staff regarding the termination of Pharmacist T.B., but such failure was not done with the intent or desire to mislead Board Staff regarding Direct Compounding's PIC. Nevertheless, Direct Compounding recognizes the severe gravamen of its lack of timely notification to Board Staff regarding the termination of Pharmacist T.B., the eighteen (18) day timeframe in which Direct Compounding did not have a PIC to oversee operation of the pharmacy, and the criticality this error created for all other material allegations made in the Amended Accusation.

12. On April 4, 2019, Direct Compounding received notification from its online security monitor that Pharmacist T.B. had attempted – after his termination – to remotely access Direct Compounding's network server and systems through the Direct Compounding website. Direct Compounding considered this unauthorized access effort to be a significant attempt on the part of Pharmacist T.B. to breach Direct Compounding's online systems, wherein Pharmacist T.B. would have unfettered access to Direct Compounding's proprietary information and data.

13. In response to the notification noted in Paragraph 12 above, and in an effort to ensure that Pharmacist T.B. did not retain an ability to access the Direct Compounding facilities

and to address the immediacy of the high concerns raised by Pharmacist T.B.'s efforts to access Direct Compounding's systems, on April 4, 2019 Direct Compounding obtained a locksmith to change all of the locks to the Direct Compounding facilities. Insofar as Ms. Gerber and Ms. Smith were both located in California at this time, Mr. Thomas was asked to meet the locksmith at Direct Compounding's business location. Mr. Thomas agreed to do so.

14. When the locksmith completed the change to all of Direct Compounding's locks, the locksmith delivered three sets of keys to Direct Compounding to Mr. Thomas. Mr. Thomas subsequently delivered one set of keys to Ms. Hernandez on or about April 8, 2019.

15. Direct Compounding's efforts to ensure that Pharmacist T.B. could no longer access its online systems or physical location were made in the exigency of Direct Compounding severing its business relationship with Pharmacist T.B. and protecting the business from potential nefarious conduct on the part of Pharmacist T.B. Asking Mr. Thomas to meet the locksmith, and the subsequent delivery of keys to Mr. Thomas, was not made with the intent of providing access to Direct Compounding by unauthorized persons or employees. Nevertheless, Direct Compounding recognizes that the consequence to the exigency of its decision-making during a tumultuous time created a second level of material allegations as set forth in the Amended Accusation.

16. On April 4, 2019, Ms. Gerber sent an email to Board Staff through the email address pharmacy@pharmacy.nv.gov requesting information and applicable forms to notify Board Staff of a change to Direct Compounding's PIC. Ms. Gerber did not receive a response to this email outreach.

17. Having not received a response from Board Staff regarding a change to Direct Compounding's PIC, Ms. Gerber subsequently worked with Mr. Thomas to identify the process

and applicable forms for notifying Board Staff of a change to Direct Compounding's PIC. Direct Compounding submitted the requisite form and notification of a change to its PIC on April 22, 2019.

18. During the period of April 4, 2019 through April 22, 2019, Mr. Thomas and Ms. Hernandez were generally instructed by Ms. Gerber to work from home rather than access the Direct Compounding facilities. Nevertheless, both Mr. Thomas and Ms. Hernandez did access the Direct Compounding facilities on limited occasions and for limited time periods between approximately April 12 – 22, 2019. Ms. Gerber was aware that both Mr. Thomas and Ms. Hernandez accessed the Direct Compounding facilities and engaged in some work while onsite—which access she believed was limited to the back-office suite and not to the pharmacy proper—but Ms. Gerber was not aware (as a result of being undereducated on regulatory requirements) that such access was (and is) prohibited by Nevada law. Direct Compounding did not intend to violate Nevada law in this regard, but it fully understands that the lack of regulatory knowledge caused a third level of material issues as alleged in the Amended Accusation.

19. During the timeframe between April 4, 2019 and April 22, 2019, Mr. Thomas and Ms. Hernandez engaged in the following work while onsite at Direct Compounding's facilities: development of marketing, policies, and procedures; development of call logs and patient tracking systems; organization of the business back offices; and general "busy work." Again, Direct Compounding's expectation was that both Mr. Thomas and Ms. Hernandez were to work from home – remotely – during this timeframe. To the best of Respondent's knowledge, neither Mr. Thomas nor Ms. Hernandez engaged in any pharmaceutical or compounding work when no pharmacist was present during this timeframe.

20. During the period of April 1, 2019 through April 22, 2019, Direct Compounding did not engage in any sales or the payment of any invoices. Direct Compounding did fulfill the dispensing of one prescription during this timeframe—entered into Direct Compounding's computer system April 17, 2019 and compounded on April 18, 2019—which occurred while Mr. Silber was present at Direct Compounding's facilities and with his oversight.

21. As noted above, Mr. Silber accepted the position of PIC for Direct Compounding on April 16, 2019, with an official payroll start date of April 22, 2019. Nevertheless, Mr. Silber was onsite at Direct Compounding's facilities for various time periods up to three (3) hours per day, on April 15 and 18, 2019, for purposes of setting up his office and reviewing general operations and policies of Direct Compounding. Mr. Silber was present on at least one occasion when Mr. Thomas engaged in compounding a pharmaceutical. In addition, Mr. Silber signed-off on at least one prescription on April 18, 2019.

22. On April 22, 2019, Mr. Silber engaged a locksmith to change all of the locks to the Direct Compounding facilities. Mr. Silber undertook this project on the advice of Board Staff investigators, who were onsite at the Direct Compounding facilities on this date. In addition, on this same date Mr. Silber and Ms. Gerber changed Direct Compounding's alarm system access and contact person to reflect Mr. Silber's authority to act on behalf of the pharmacy as its PIC.

23. Among his first tasks for Direct Compounding, Mr. Silber prepared an accounting of all pharmaceuticals and compounding ingredients in the pharmacy's inventory. Further to this task, Mr. Silber prepared and filed a Change of Managing Pharmacist Inventory with Board Staff on April 22, 2019, identifying the opening-day inventory as of this date. At all times relevant to this matter, all Schedule II controlled substances identified in this inventory report

were locked in Direct Compounding's safe, to which only Direct Compounding's PIC had (and has) access.

24. Direct Compounding respectfully requests that the Board consider that the events alleged in the Amended Accusation occurred over two years ago, and that the events giving rise to the Amended Accusation occurred in an eighteen (18) day timeframe. Direct Compounding is acutely aware that the allegations of the Amended Accusation are significant, but outside of the timeframe of these allegations Direct Compounding has not had any disciplinary issues with the Board and it has operated for the two-plus years following April 22, 2019 without incident.

25. Mr. Silber respectfully requests that the Board recognize that the majority of allegations set forth in the Amended Allegation are unrelated to his hiring and employment as Direct Compounding's PIC. In response to the First Cause of Action, Mr. Silber states as follows:

a. As set forth in Paragraph 10 above: (i) Direct Compounding offered Mr. Silber the position of PIC on or about April 16, 2019; (ii) Mr. Silber accepted this position, with an official payroll start date of April 22, 2019 but an actual onsite start date of April 15, 2019; (iii) Mr. Silber executed the form Pharmacy Manager's Responsibilities on April 22, 2019, and (iv) Mr. Silber submitted the Change of Managing Pharmacist Form and identified his start date as PIC, as of April 22, 2019.

b. Mr. Silber denies that he had any knowledge that either Mr. Thomas or Ms. Hernandez were unlawfully accessing Direct Compounding's pharmacy. Mr. Silber acknowledges that, or about April 16, 2019, he became aware that both Mr. Thomas and Ms. Hernandez were accessing Direct Compounding's premises without a designated onsite PIC.

c. Mr. Silber acknowledges that, on or about April 18, 2019, he oversaw and signed-off on at least one compounding and prescription of a pharmaceutical while onsite at Direct Compounding's facilities.

26. Direct Compounding and Mr. Silber respectfully request that the Board consider each of these mitigating circumstances in evaluating the Amended Accusation, and that any remedial measures be limited to constructive and productive results. Direct Compounding and Mr. Silber do not believe that the allegations of the Amended Accusation warrant suspension or revocation of any licenses or certificates of registration. Direct Compounding and Mr. Silber are contrite as to the allegations of the Amended Accusation—which were isolated to one series of events over an eighteen-day period in 2019—and they are ready, willing, and able to work in good faith with the Board and Board Staff to ensure no further occurrences such as those set forth in the Amended Accusation recur.

Respectfully submitted this 24th day of June, 2021.

James D. Boyle, Esq.
Nevada Bar No. 08384
Holley Driggs Ltd.
400 South Fourth Street, 3rd Floor
Las Vegas, Nevada 89101
(702) 791-0308
Email: jboyle@nevadafirm.com

Attorneys for Respondents Direct Compounding and Outsourcing, LLC and Scot M. Silber, R.Ph.

CERTIFICATE OF SERVICE

I certify that on the 24th day of June, 2021, I caused the document entitled **ANSWER AND NOTICE OF DEFENSE TO AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION** to be served on the following parties:

Attorneys of Record	Parties Represented	Method of Service
Brett Kandt, Esq. Courtney K. Lee, Esq. David Wuest Nevada State Board of Pharmacy 985 Damonte Ranch Pkwy, Suite 206 Reno, Nevada 89521 Email: bkandt@pharmacy.nv.gov c.lee@pharmacy.nv.gov dwuest@pharmacy.nv.gov+	Nevada State Board of Pharmacy	☐ Personal Service ■ Email/E-File ☐ Fax Service ■ Mail Service

DATED this 24th day of June, 2021.

Kelly MacDonald

An Employee of Holley Driggs Ltd.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DIRECT COMPOUNDING AND OUTSOURCING, LLC Pharmacy License No. PH04006, SCOT SILBER, RPH, Certificate of Registration No. 08362, MICHAEL THOMAS, PT Certificate of Registration No. PT05905, KRYSTAL HERNANDEZ, PT Certificate of Registration No. PT10671, Respondents.	CASE NOS. 19-070-PH-S 19-070-RPH-S 19-070-PT-A-S 19-070-PT-B-S **DECLARATION OF ELLIE GERBER IN SUPPORT OF ANSWER AND NOTICE OF DEFENSE TO AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

I, Ellie Gerber, hereby state and declare as follows:

1. I make this Declaration in support of an Answer and Notice of Defense to Amended Notice of Intended Action and Accusation (the "Amended Accusation") submitted on behalf of Direct Compounding and Outsourcing, LLC ("Direct Compounding") and on behalf of Scot M. Silber, R.Ph. ("Mr. Silber"). I am over the age of eighteen years and competent to testify as to the matters set forth herein. I make this Declaration upon personal knowledge, or upon information and belief where so indicated.

2. Direct Compounding was incorporated with the Nevada Secretary of State on June 12, 2017. I am a fifteen percent owner of Direct Compounding. Alicia Smith is the other owner of Direct Compounding, controlling eighty-five percent of the ownership interests in the business.

3. At the time of incorporating Direct Compounding and throughout the relevant timeframe of the Amended Accusation, both I and Ms. Smith were novice owners of a pharmacy and were, in full candor to the Board, undereducated with regard to state and federal statutory and regulatory obligations applicable to owners of a licensed and registered pharmacy. While I have prior experience in the business of pharmacy, my experience was largely directed toward finance, marketing, infrastructure development, and general business operations. Neither I nor Ms. Smith had any prior experience regarding any depth of regulatory know-how and compliance.

4. My and Ms. Smith's success—and, by extension, of Direct Compounding as well—in gaining competency in operating a licensed pharmacy, is best evidenced through the complete absence of investigatory or disciplinary issues with state and federal authorities subsequent to the events addressed in the Amended Accusation.

5. Direct Compounding initially hired Pharmacist T.B. as its Pharmacist-in-Charge ("PIC"). Direct Compounding employed Pharmacist T.B. as its PIC from June 12, 2017 through approximately April 4, 2019. Due to our inexperience in the ownership of a pharmacy, Ms. Smith and I placed full faith and responsibility in Pharmacist T.B. to oversee, operate, manage, and supervise Direct Compounding, and further to ensure Direct Compounding was compliant with all statutory and regulatory obligations.

6. For the time period of June 2017 through April 2019, Direct Compounding did not receive any disciplinary notifications or legal actions from either the Board or the United States Food and Drug Administration, or from any other state or federal agencies or oversight personnel. Neither has Direct Compounding received any disciplinary notifications or other legal actions from the Board or the FDA, or from any other state or federal agencies or oversight

personnel, since April 2019. Direct Compounding complied with all recommendations by Board Staff and federal agencies pursuant to regulatory inspections.

7. Direct Compounding hired Michael Thomas on November 9, 2018 and he was employed through October 22, 2020. Direct Compounding hired Krystal Hernandez on July 17, 2018 and she was employed through June 4, 2020. Neither Mr. Thomas nor Ms. Hernandez is presently employed with Direct Compounding.

8. On or about April 4, 2019, Direct Compounding terminated Pharmacist T.B., based upon multiple issues which required an immediate separation of Pharmacist T.B. from employment with Direct Compounding. Direct Compounding's separation from Pharmacist T.B. was considerably tumultuous and confrontational, which point was exacerbated by my and Ms. Smith's residing in California at the time of termination.

9. Immediately thereafter, Direct Compounding began its search for a new PIC to replace Pharmacist T.B. On April 15, 2019, upon my return to Nevada, I met Mr. Silber at the Direct Compounding business offices for the purposes of interviewing him for the position of PIC. Mr. Silber accepted the position of PIC on April 16, 2019, with an official payroll start date of April 22, 2019 and an actual start date of April 15, 2019.

10. On April 4, 2019, Direct Compounding received notification from its online security monitor that Pharmacist T.B. had attempted – after his termination – to remotely access Direct Compounding's network server and systems through the Direct Compounding website. Direct Compounding considered this unauthorized access effort to be a significant attempt on the part of Pharmacist T.B. to breach Direct Compounding's online systems, wherein Pharmacist T.B. would have unfettered access to all of Direct Compounding's proprietary information and data. A true and accurate copy of this notification is attached hereto as Exhibit A-1.

11. In an effort to ensure that Pharmacist T.B. did not retain an ability to access the Direct Compounding facilities, on April 4, 2019 Direct Compounding obtained a locksmith to change all of the locks to the Direct Compounding facilities. Insofar as both Ms. Smith and I were located in California at this time, Mr. Thomas was asked to meet the locksmith at Direct Compounding's business location. Mr. Thomas agreed to do so.

12. As I understand subsequent events, when the locksmith completed the change to all of Direct Compounding's locks, the locksmith delivered three sets of keys to Direct Compounding to Mr. Thomas. Mr. Thomas subsequently delivered one set of keys to Ms. Hernandez on or about April 8, 2019.

13. Direct Compounding's efforts to ensure that Pharmacist T.B. could no longer access its online systems or physical location were made in the exigency of Direct Compounding severing its business relationship with Pharmacist T.B. and protecting the business from potential nefarious conduct on the part of Pharmacist T.B. Asking Mr. Thomas to meet the locksmith, and the subsequent delivery of keys to Mr. Thomas, was not made with the intent of providing access to Direct Compounding to unauthorized persons or employees. However, in hindsight Direct Compounding recognizes that having Mr. Thomas meet the locksmith and obtain the keys to the Direct Compounding facilities was made in error and is a precipitating cause of the Board's Amended Accusation against Direct Compounding and the other Respondents.

14. Following Direct Compounding's termination of Pharmacist T.B., I sent an email to Board Staff on April 4, 2019 through the email address pharmacy@pharmacy.nv.gov, requesting information and applicable forms to notify Board Staff of a change to Direct Compounding's PIC. I did not receive a response to this email outreach. A true and accurate copy of this email is attached hereto as Exhibit A-2.

15. Having not received a response from Board Staff regarding a change to Direct Compounding's PIC, I subsequently worked with Mr. Thomas to identify the process and applicable forms for notifying Board Staff of a change to Direct Compounding's PIC. Direct Compounding submitted the requisite form and notification of a change to its PIC on April 22, 2019.

16. During the period of April 4, 2019 through April 22, 2019, I instructed Mr. Thomas and Ms. Hernandez to work from home rather than access the Direct Compounding facilities. Nevertheless, I was aware both Mr. Thomas and Ms. Hernandez did access the Direct Compounding facilities on limited occasions and for limited time periods between approximately April 12 – 22, 2019. I was also aware that both Mr. Thomas and Ms. Hernandez accessed the Direct Compounding facilities and engaged in some work while onsite—which access I believed was limited to the back-office suite and not to the pharmacy proper. I was not aware (as a result of being undereducated on regulatory requirements) that such access was (and is) prohibited by Nevada law. Direct Compounding did not intend to violate Nevada law in this regard.

17. To the best of my knowledge, during the timeframe between April 4, 2019 and April 22, 2019, Mr. Thomas and Ms. Hernandez engaged in the following work while onsite at Direct Compounding's facilities: development of marketing, policies, and procedures; development of call logs and patient tracking systems; organization of the business back offices; and general "busy work." Again, Direct Compounding's expectation was that both Mr. Thomas and Ms. Hernandez were to work from home – remotely – during this timeframe. To the best of my knowledge, neither Mr. Thomas nor Ms. Hernandez engaged in any pharmaceutical or compounding work when no pharmacist was present during this timeframe.

18. During the period of April 1, 2019 through April 22, 2019, Direct Compounding did not engage in any sales or the payment of any invoices. A true and accurate copy of Direct Compounding's Sales and Product Service Detail is attached hereto as Exhibit A-3.

19. I am aware that on April 22, 2019, Mr. Silber engaged a locksmith to change all of the locks to the Direct Compounding facilities. On this same date, I worked with Mr. Silber to ensure that the alarm system for Direct Compounding was reset and that Mr. Silber was designated as the primary contact person for the alarm company. Subsequently, Direct Compounding has changed its internal policies to ensure that I also personally receive all notifications and correspondence from the alarm company regarding the performance and troubleshooting issues related to Direct Compounding's alarm system.

20. In or about late-March 2019, I received an invoice from Pharmacist T.B. for 24 10 ML / VL of Testosterone Cyplonate Injectable MDV 200 MG / M. A true and accurate copy of this invoice is attached hereto as Exhibit A-4. To the best of my knowledge, this is the controlled substance of which the Board complains in the Amended Accusation. To this point, it was my understanding that Pharmacist T.B. placed the inventory of this pharmaceutical in Direct Compounding's safe, as was the required policy of Direct Compounding regarding inventorying of controlled substances. Neither Ms. Smith nor I was aware that Pharmacist T.B. had not placed the inventory of this pharmaceutical in Direct Compounding's safe.

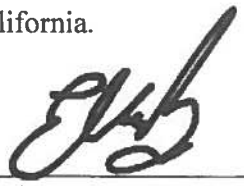
21. On April 30, 2019, I received notification from Mr. Thomas that Pharmacist T.B. had ordered one 100 G quantity of Testosterone Non-Micro, USP, CIII, and one 100 G quantity of Testosterone Cyplonate, USP, III, from B&B Pharmaceuticals, Inc. True and accurate copies of these order invoices are attached hereto as Exhibit A-5. Insofar as Pharmacist T.B. did not

notify me or Ms. Smith of the pharmaceuticals he was ordering, this email from Mr. Thomas is the first notice Ms. Smith and I received regarding the ordering of these pharmaceuticals.

22. Direct Compounding respectfully requests that the Board consider that the events alleged in the Amended Accusation occurred over two years ago, and that the events giving rise to the Amended Accusation occurred in an eighteen (18) day timeframe. Direct Compounding is acutely aware that the allegations of the Amended Accusation are significant, but outside of the timeframe of these allegations Direct Compounding has not had any disciplinary issues with the Board and it has operated for the two-plus years following April 22, 2019 without incident.

I declare under penalty of perjury under the laws of the Nevada that the foregoing is true and correct.

Executed this 24th day of June, 2021 in Carlsbad, California.



Ellie Gerber

TAB A-1

TAB A-1

[redacted]

From: **G Suite Alerts** <gsuite-alerts-noreply@google.com>
Date: Thu, Apr 4, 2019 at 12:01 PM
Subject: Suspicious Login
To: <egerber@directcompounding.com>

G Suite

This is to inform you that Google has detected a suspicious login for tbrown@directcompounding.com in your domain directcompounding.com.

User: tbrown@directcompounding.com
IP from which the login attempt was detected: 70.189.245.216

Go to Alert Center to see more details for this alert. See also the G Suite Admin Help Center.

Go to Alert Center

You have received this important update about your G Suite account because you designated this email address as a primary contact for mandatory service communications in your Google Admin console profile.

Google LLC 1600 Amphitheatre Parkway Mountain View, CA 94043

TAB A-2

TAB A-2

[redacted]

From: **Ellie Gerber** <egerber@directcompounding.com>
Date: Thu, Apr 4, 2019 at 6:15 AM
Subject: Questions for existing pharmacy
To: pharmacy@pharmacy.nv.gov <pharmacy@pharmacy.nv.gov>

Hello,

Can you please direct me to the forms needed to complete the following for our pharmacy:

1) We need to update our PIC, is there a form for that or do I just email the personnel change?

2) We have updated our corporate structure to satisfy the board of California for non-resident applications, does that need to be updated with the Nevada board as well?

3) I had sent the verification form necessary for our non-resident California application, just wanted to make sure it was received and see if there is an estimated return date.

Thank you,
Ellie Gerber
Direct Compounding, LLC
Direct - 760-500-0271
--

DIRECT compounding

Ellie Gerber
C: 760-500-0271

--

DIRECT compounding

TAB A-3

TAB A-3

Direct Compounding and Outsourcing

Sales by Product/Service Detail

April 1-22, 2019

DATE	TRANSACTION TYPE	NUM	CUSTOMER	MEMO/DESCRIPTION	QTY	SALES PRICE	AMOUNT	BALANCE

TAB A-4

TAB A-4

IN SOURCE

BOX CONTENT LIST

INVOICE#	INVOICE DATE
63513703	3/25/19
CUSTOMER#	BOX# / PAGE#
3802737	1 of 1 / 1
CUSTOMER PO#	
ORDER#	ORDER DATE
74171377	03/15/19

SHIP TO
DIRECT COMPOUNDING PHARMACY
1850 WHITNEY MESA DR STE 180
HENDERSON NV 89014-2093

BILL TO
Direct Compounding Pharmacy
1850 Whitney Mesa Dr Ste 180
Henderson,NV 89014-2093

T.C.

LOCATION CODE	SHIPPED QTY	EXP. CODE	UNIT SIZE	DESCRIPTION & STRENGTH	ITEM CODE	LINE NO
D-21-02-34	24	05/19	10ML/VL	TESTOSTERONE CYPI INJ MDV 200MG/M 00143972601 NDC#:0143-9726-01/00143-9726-01 LOT#/Exp:1805099.1 04/30/20 See Terms of Sale for (DSCSA) Compliance Message Details	126-2635	1

.GO TO YOUR ONLINE ACCOUNT TO RETRIEVE THIS SDS, 105MK41 -
IF YOU CANNOT ACCESS ONLINE OPTIONS OR TO OPT OUT OF
ELECTRONIC SDS CALL (800) 472-4346.

WELCOME TO E-SDS. BEGINNING TODAY, PAPER SDS WILL NO
LONGERBE INCLUDED WITH YOUR ORDER. GO TO YOUR ONLINE ACCOUNT
AND CLICK ON SDS LOOK-UP ON THE NAVIGATION PANE. IF YOU
DON'T HAVE AN ONLINE ACCOUNT, GO TO WWW.HENRYSCHEIN.COM AND
CLICK ONCREATE AN ONLINE ACCOUNT. TO OPT OUT OF OUR
ELECTRONIC SDS PROGRAM AND CONTINUE RECEIVING SDS SHEETS
WITH YOUR ORDERS PLEASE CALL CUSTOMER SERVICE AT (800)
472-4346.

INSOURCE D.C. Dea#: RI0166149
Customer Dea#: FD8137968

Insource Inc.
80 SUMMIT VIEW LANE
BASTIAN ,VA 24314

Donna Nunn
3-25-19

TotQty- 24

OFFICE USE ONLY

BATCH# 46673-002

Size:#E2

WT - 1

FREIGHT INSTRUCTIONS UPS 1377

PED

TAB A-5

TAB A-5

B&B Pharmaceuticals Inc.

8591 Prairie Trail Drive - Ste C-600 - Englewood, CO 80112
(800) 499-3100 - www.bbpharm.net

INVOICE

Page 1

Bill-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Ship-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Sell-to Customer No.	C02227	Invoice No.	SPI17511
Bill-to Customer No.	C02227	Order No.	SO18708
DEA License No.	FD8137968	Customer PO No.	
Pharmacy License No.	PH04006	Order Date	4/17/19
B&B DEA License No.	RB0223696	Invoice Date	4/17/19
B&B Wholesaler No.	WH01747	Due Date	5/17/19
Shipment Method	Ground	Payment Terms	NET30
Salesperson	Ian McBride	Payment Method	CHECK

No.	Description	Quantity	Unit of Measure	Unit Price	Lot No.	NDC No.	Amount
700221	Testosterone Non-Micro., USP, CIII	1	100 G	195.00	18L18-BB02-PR00581	63276-9698-05	195.00

Total USD $ **195.00**

** All API's are supplied in BULK RAW powdered form**

Remit Payment to:
B&B Pharmaceuticals Inc.
8591 Prairie Trail Drive - Ste C-600
Englewood, CO 80112

Thank you for your business. B&B Pharmaceuticals strives to provide the best in product quality and customer service.
If you are unsatisfied for any reason please call (800) 499-3100.

B&B Pharmaceuticals Inc.

8591 Prairie Trail Drive - Ste C-600 - Englewood, CO 80112
(800) 499-3100 - www.bbpharm.net

INVOICE

Bill-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Ship-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Sell-to Customer No.	C02227	Invoice No.	SPI17265
Bill-to Customer No.	C02227	Order No.	SO18475
DEA License No.	FD8137968	Customer PO No.	
Pharmacy License No.	PH04006	Order Date	4/1/19
B&B DEA License No.	RB0223696	Invoice Date	4/1/19
B&B Wholesaler No.	WH01747	Due Date	5/1/19
Shipment Method	Ground	Payment Terms	NET30
Salesperson	Ian McBride	Payment Method	CHECK

No.	Description	Quantity	Unit of Measure	Unit Price	Lot No.	NDC No.	Amount
700212	Testosterone Cypionate, USP, CIII	1	100 G	189.00	19A15-BB05-PR00596	63275-9982-05	189.00

Total USD $ **189.00**

** All API's are supplied in BULK RAW powdered form**

Remit Payment to:
B&B Pharmaceuticals Inc.
8591 Prairie Trail Drive - Ste C-600
Englewood, CO 80112

Thank you for your business. B&B Pharmaceuticals strives to provide the best in product quality and customer service.
If you are unsatisfied for any reason please call (800) 499-3100.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DIRECT COMPOUNDING AND OUTSOURCING, LLC Pharmacy License No. PH04006, SCOT SILBER, RPH, Certificate of Registration No. 08362, MICHAEL THOMAS, PT Certificate of Registration No. PT05905, KRYSTAL HERNANDEZ, PT Certificate of Registration No. PT10671, Respondents.	CASE NOS. 19-070-PH-S 19-070-RPH-S 19-070-PT-A-S 19-070-PT-B-S **DECLARATION OF SCOT M. SILBER, R.Ph. IN SUPPORT OF ANSWER AND NOTICE OF DEFENSE TO AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

I, Scot M. Silber, R.Ph., hereby state and declare as follows:

1. I make this Declaration in support of an Answer and Notice of Defense to Amended Notice of Intended Action and Accusation (the "Amended Accusation") submitted on behalf of me personally and on behalf of Direct Compounding and Outsourcing, LLC ("Direct Compounding"). I am over the age of eighteen years and competent to testify as to the matters set forth herein. I make this Declaration upon personal knowledge, or upon information and belief where so indicated.

2. I am a licensed and registered pharmacist with the Nevada State Board of Pharmacy pursuant to Certificate of Registration No. 08362. I have practiced pharmacy in the State of Nevada for over thirty-seven years.

3. On April 15, 2019, I met Ellie Gerber – an owner of Direct Compounding – at the business offices for the purposes of interviewing for the position of Pharmacist-in-Charge

("PIC"). I accepted the position of PIC on April 16, 2019, with an official payroll start date of April 22, 2019 and an actual start date of April 15, 2019. During the week of April 15, 2019 through April 22, 2019, I was onsite at Direct Compounding's facilities for various time periods up to three (3) hours per day, for purposes of setting up my office and reviewing general operations and policies of Direct Compounding.

4. I was present on at least one occasion when Michael Thomas engaged in compounding a pharmaceutical. In addition, I signed-off on one prescription dispensed on April 18, 2019. A true and accurate copy of Direct Compounding's Log of Scripts for the time period April 3, 2019 through April 21, 2019 is attached hereto as Exhibit B-1, which identifies the prescription that was entered into Direct Compounding's computer system on April 17, 2019 and dispensed on April 18, 2019.

5. In response to the First Cause of Action alleged in the Amended Accusation:

a. Direct Compounding offered me the position of PIC on or about April 16, 2019; (ii) I accepted this position, with an official payroll start date of April 22, 2019 but an actual onsite start date of April 15, 2019; (iii) I completed and executed the form Pharmacy Manager's Responsibilities on April 22, 2019, and (iv) I completed and submitted the Change of Managing Pharmacist Form and identified his start date as PIC, as of April 22, 2019.

b. I did not have any knowledge that either Mr. Thomas or Ms. Hernandez were unlawfully accessing Direct Compounding's pharmacy at any time during the timeframe relevant to the Amended Accusation. I acknowledge that, or about April 16, 2019, I became aware that both Mr. Thomas and Ms. Hernandez

were accessing Direct Compounding's premises without a designated onsite PIC.

6. On April 22, 2019, I engaged a locksmith to change all of the locks to the Direct Compounding facilities. I undertook this project on the advice of Board Staff investigators, who were onsite at the Direct Compounding facilities on this date. In addition, on this same date I worked with Ms. Gerber to change Direct Compounding's alarm system access and contact person to reflect Mr. Silber's authority to act on behalf of the pharmacy. True and accurate copies of invoices and reports related to these two projects are attached hereto as Exhibits B-2 and B-3, respectively.

7. On April 22, 2019, I also prepared an accounting of the controlled substance pharmaceuticals and compounding ingredients in the pharmacy's inventory. I prepared and filed a Change of Managing Pharmacist Inventory with Board Staff on April 22, 2019, identifying the opening-day controlled substances inventory as of this date. A true and accurate copy of this Change of Managing Pharmacist Inventory is attached hereto as Exhibit B-4.

8. To the best of my knowledge, at all times prior to my engagement as PIC, Direct Compounding maintained its inventory of all Schedule II controlled substances in its safe, to which only the PIC had access. Subsequent to my engagement as PIC, Direct Compounding maintained all of its inventory of Schedule II controlled substances in its safe. I had the only access to this safe as Direct Compounding's PIC, through June 1, 2021 and my resignation as PIC. Following my resignation as Direct Compounding's PIC, and to the best of my knowledge, Direct Compounding's new PIC has had the only access to this safe.

9. On April 22, 2019, I also prepared and submitted a Change of Managing Pharmacist Form and Pharmacy Manager's Responsibilities acknowledgement to the Nevada

State Board of Pharmacy. A true and accurate copy of the Change of Managing Pharmacist Form and the Pharmacy Manager's Responsibilities acknowledgment are attached hereto as Exhibits B-5 and B-6, respectively.

10. I resigned my position as PIC for Direct Compounding effective June 1, 2021.

I declare under penalty of perjury under the laws of the Nevada that the foregoing is true and correct.

Executed this 24th day of June, 2021 in Henderson, Nevada.

SM Silber R.Ph.

Scot M. Silber, R.Ph.

TAB B-1

TAB B-1

LOG OF SCRIPTS COMBINED PRESCRIPTIONS Schedule: ALL
1 line report
Printed 5/26/2021
Page 1 **Prescriptions filled between 4/4/2019 and 4/21/2019**

Direct Compounding
1850 Whitney Mesa Drive Suite 180
Henderson, NV 89014 Ph. 888-341-0157
NCPDP #2995388 FD8137968

Sorted by: Fill date

Rx number	Date disp	Date written	Patient	Qty and Drug	Doctor	Pharmacist Initials	Re/Rm	Total	Tax	Cost	% profit
C00100035	4/17/2019	3/19/2019	PEARCE, STEVEN	30 OXANDROLONE 25MG CAPSULE	ULEVICH, LYNNE	RPH	2 1	$100.00	0.00	$38.20	61.80%

1 prescriptions in report

Total price	$100.00
Total price (Insurance pay)	$0.00
Total price (Copay)	$100.00
Total tax	$0.00
Total cost	$38.20
Total profit	$61.80
Average price	$100.00
Average cost	$38.20
% profit margin	61.80%
Average profit per Rx	$61.80
Total price override	($12.50)

1 Pharmacist's signature _____ R.Ph 5/26/21 Date 5/26/2021
My signature on this daily report verifies that the data on this report is complete and correct to the best of my knowledge

Signature 1_____
Signature 2_____
Signature 3_____
Signature 4_____
Signature 5_____
Signature 6_____
Signature 7_____
Signature 8_____

TAB B-2

TAB B-2

SILVERSTATE LOCKSMITH LTD.

№ 6895

800 N. Rainbow Blvd., Suite 148
Las Vegas, NV 89107
702-445-3758
www.Silverstatelocksmith.com

DATE: 4/22/19.

VISA/MASTER CARD/AMERICAN EXPRESS
AUTH CODE: 062417

CUSTOMER DETAILS

NAME Direct Compounding	PHONE 702-217-3866
CREDIT/DEBIT CARD BILLING ADDRESS	SERVICE ADDRESS 1850 Whitney Mesa Dr #180
D.L/I.D NUMBER	ADDITIONAL INFO

IF VEHICLE

YEAR	MAKE	MODEL
TAG	VIN	

PARTS/MATERIALS

QTY	DESCRIPTION	PRICE	AMOUNT
	DUPLICATE KEYS		
	ORIGINAL KEYS		
	DEADBOLT (TYPE)		
	KNOBSET (TYPE)		
	LOCKSET (TYPE)		
	OTHER		

LABOR

QTY	DESCRIPTION	PRICE	AMOUNT
	LABOR TO INSTALL/FIX ABOVE		
6	RE-KEY (CYLINDER COMBINATION CHANGE)	25 00	150 00
	SAFE OPENING/COMBINATION CHANGE		
	EMERGENCY /HOUSE/BUSINESS/VEHICLE/ LOCKOUT SERVICE		
1	SERVICE CALL		65 00
	OTHER -		

Month warranty

SUB TOTAL	215	00
TAX		
TOTAL	215	00

AUTHORIZATION OF SERVICE /INCIDENTAL DAMAGE RELASE/ COMPLETION OF SERVICE

By signing this invoice I hereby certify that I have given the authority to order the service/lock/key/security job as Described above to SilverState Locksmith\technician and I agree to pay fully to the SilverState Locksmith\technician all charges above. I also hereby that I am fully aware of the fact that the estimate Has been provided to me according to the information provided to the locksmith and in the event of SilverState Locksmith/technician discovering additional problems and/or complications additional charges may be applied.

By and through my signature below, I express knowledge and affirm that I have been advised, understand And accept that incidental damage including but not limited to cosmetic and/or mechanical damage to locks, doors Windows and walls can and may occur during inspection, maintenance, repair and/or replacement services. I further acknowledge and agree that the SilverState Locksmith Company and/or the technician shall not be liable in any way for such damage Or associated losses and that I shall remain fully obligated to pay SilverState Locksmith/technician in full prior to or upon completion of the Service(s) as described above

COMPLETION OF SERVICE

By signing this invoice I hereby certify that I was provided the service/lock/key/security job complete to my full satisfaction and Have no further complaints or demands regarding the service.

Signature	Name	date 4/22/19

TAB B-3

TAB B-3

[redacted]

From: Ruth Adams <rutha@asapnv.com>
Date: Mon, Apr 22, 2019 at 3:19 PM
Subject: Fw: alarm system
To: egerber@directcompounding.com <egerber@directcompounding.com>, fsilber@directcompounding.com <fsilber@directcompounding.com>

Hello,

The alarm system is back up and running. I making the changes you requested but I do need them in writing. Please confirm the contact person to be deleted and the name of the person to be added to the account. Code changes are complete.

Your central station number is 855-955-2727

Ruth Adams

aka **The Las Vegas Security Girl** - *I may not be a super hero... But I will protect your home like you had one.*

ASAP Security - ADT Authorized Dealer

3170 Polaris Ave Ste 4

Las Vegas, NV 89102

702-870-8880 Office

702-351-8210 Cell

TAB B-4

TAB B-4

Controlled Inventory

Schedule 3-5 Powders

			Quantity
HCG	3974-2327-01 Meditech	6/4	2 mL
HCG/Triturate 100,000U/gm			9.5 gm
Ketamine	63275-9980-05	9-23	10 gm
Oxandrolone	62991-2699-03	11-20	17.5 gm
Stanozolol	62991-306-89	9-21	28.35 gm
Testosterone Cypionate	63275-7782-05	7-8-20	95 gm
Testosterone USP	63276 9988-05	9-1801	100 gm

Schedule 2 Powders

Hydromorphone HCL Powder	63275-2025-4	5/811 23	25 gm S
Morphine Sulfate Powder	63275-1025-4	10/20	25 gm S
Fentanyl Citrate Powder	63275-5100-2	2/28/23	25 gm S

Schedule 3-5 Compounded

Stanozolol 25mg Lozenge	Cmpd		36
HCG 1000U/ML 6ML Vial	Cmpd	5/3/19	8

Schedule 3-5 Traditional

Testosterone Cyp. 200mg/ml		62756-016-40	6-19	13
11	21	0143-9726-01	4-20	24

Signature RPh	Date 4-22-19

Nandrolone USP 63275-9888-05 12/22 100 gm

Nandrolone USP 63275 9889-4 12/22 10 gm

Oxandrolone Caps Cmpd 90 Caps

Test Cip /grape Seed Cmpd 10ml 1ea

Change of Managing RPh - Start of Day Inventory

4-22-19

TAB B-5

TAB B-5

NEVADA STATE BOARD OF PHARMACY

431 W PLUMB LANE – RENO, NV 89509 - (775) 850-1440

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

CHANGE OF MANAGING PHARMACIST FORM

Registration Fee: $50.00

(non-refundable money order or cashier's check only, no cash or business check's)

*This form is only required for pharmacies physically located in Nevada. We only require written notification from an out-of-state pharmacy for a manager change.

General Information

**Nevada Pharmacy Board License #: PH 04006
**(Do not use your RPH, NPI or DEA number. Number begins with a PH, IA, IB)

Pharmacy Name: Direct Compounding and Outsourcing LLC Store #: _____

Address: 1850 Whitney Mesa #180

City: Henderson State: * NV Zip: 89014

Telephone: 702-871-0208 Fax: 702-342-0335

New Managing Pharmacist Name: Scot Silber

License #: 08362 Date Started: 4-22-19

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?....	☐	☒
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?.....	☐	☒
2. Been the subject of an administrative action whether completed or pending in any state?	☒	☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.....	☐	☒

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide documentation:

Board Administrative Action:	State		Case #:	
	NV	10-17-2012	11-090-PH-5	
Criminal Action:				

TAB B-6

TAB B-6

PHARMACY MANAGER'S RESPONSIBILITIES

(PHARMACY MANAGER, MUST READ, SIGN AND DATE THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220).

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282; NAC 639.510; NAC 639.473(2).

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NRS 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254(2)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11; NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from the last fill date for original paper prescription). (NRS 639.236; NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268; NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286; NAC 639.487)

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature of New Managing Pharmacist (no stamps or copies) — Date: 4-22-19

Board Use Only
Date Received: _____ Amount: _____

Posted 6/30/2011

Nevada State Board of Pharmacy
431 W Plumb Lane – Reno, NV 89509 – 775-850-1440
bop.nv.gov

Nevada
(For locations located in the State of Nevada)
PHARMACYAPPLICATION
INFORMATION AND CHECKLIST

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Please understand we cannot and will not accept incomplete applications. Review the application and return all required fees and documentation with the completed application.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please note the application/documentation deadline date is on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications will be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, the application will be returned.

For a location or name change of an out-of-state pharmacy, we only require notification in writing. A new application is only required if changing ownership of 50% or greater.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP
You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

- Complete all required pages of the application. Must be original signature(s), no copies or stamps.
- Registration fee of $500.00. This fee is non-refundable and non-transferable. The fee is payable by money order or cashier's check only, we do not accept personal checks, business checks, cash or credit cards. If the application is received with a personal, business check or cash, it will be returned and will delay the processing of the application. Fee made payable to: Nevada State Board of Pharmacy
- Statement of Responsibility. This is page 10 included with the application

- Statement of Responsibility - Managing Pharmacist – (2 pages) The managing pharmacist must be registered with the Nevada State Board of Pharmacy and live in Nevada. Pages 11a and 11b.

- Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate of Corporate status is obtained from the Secretary of State's office in the State where incorporated. This Certificate of Corporate status must be dated within the last 6 months.

- Addendum to Pharmacy Application – Internet. This addendum is required if you will be providing internet services. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

REQUIRED INFORMATION FOR ALL TYPES OF OWNERSHIP

An application for Nevada pharmacy requires Board approval. Upon receipt of the completed application, documentation and fee, your application can be placed on the agenda of the next regularly scheduled Board meeting. The current board meeting schedule is available on the website under the "Calendar of Upcoming Boards & Committee Meetings".

http://bop.nv.gov/board/ALL/Board_Meeting_Schedule/

Appearance(s) at the board meeting may be required. If you have never operated a pharmacy in Nevada before, you will be required to appear at a scheduled board meeting. If an appearance is required, you will be informed by way of confirmation letter two (2) weeks prior to the meeting. Otherwise assume an appearance will not be necessary.

If the application is approved at the scheduled meeting a letter with the information needed to schedule the required pre-opening inspection will be mailed within 15 days from the date of the meeting

Any change of ownership and/or location change, will require a new application and $500.00 fee. If the address changes, a pre-opening inspection will be required.

Upon board approval and satisfactory inspection a license will be issued and mailed within 15 days from the date of the inspection. A license number will not be provided until the inspection has been completed.

This license is renewed in October of even numbered years, no matter when the license is issued. Fees are not pro-rated.

Please access the applicable laws on the website under "Nevada Statues & Regulations" tab.

If you have any questions, contact the licensing specialist in the Reno office at (775) 850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐New Pharmacy or ☐Ownership Change (Provide current license number if making changes: PH____
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: _____

Physical Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: _____ Fax: _____

Toll Free Number: _____ E-mail: _____

Website: _____

Managing Pharmacist: _____ License Number: _____

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☐	Retail	☐	Off-site Cognitive Services
☐	Hospital (# beds ____)	☐	Parenteral
☐	Internet	☐	Parenteral (outpatient)
☐	Nuclear	☐	Outpatient/Discharge
☐	Ambulatory Surgery Center	☐	Mail Service
☐	Community	☐	Long Term Care
☐	Other: _____	☐	Sterile Compounding
		☐	Non Sterile Compounding
All boxes must be checked		☐	Mail Service Sterile Compounding
For the application to be complete		☐	Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☐

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☐

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☐

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

_____

Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____

Print Name of Authorized Person Date

Board Use Only Date Processed: _____ Amount: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Hours of Operation for the pharmacy:

Monday thru Friday _____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) _____
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday _____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a non publicly traded corporation continued

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General _____ Limited _____

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Partnership Name: _____

Mailing Address: _____

City, State Zip Code: _____

Telephone Number: _____ Fax Number: _____

Contact Person: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday _____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a partnership continued

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: _____ Fax: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday _____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a sole owner

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, _____

Responsible Person of _____

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

_____

Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____

Print Name of Authorized Person Date

Managing Pharmacist

Pharmacist Name: _____ License #: _____

Pharmacy Name: _____

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☐
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☐
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☐
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☐

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____
County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

_____ _____

Signature Date

TAB A-4

TAB A-4

Direct Compounding and Outsourcing

Sales by Product/Service Detail

April 1-22, 2019

DATE	TRANSACTION TYPE	NUM	CUSTOMER	MEMO/DESCRIPTION	QTY	SALES PRICE	AMOUNT	BALANCE

TAB A-5

TAB A-5

IN SOURCE

BOX CONTENT LIST

INVOICE#	INVOICE DATE
63513703	3/25/19
CUSTOMER#	BOX#	PAGE#
3802737	1 of 1	1
CUSTOMER PO#	
ORDER#	ORDER DATE
74171377	03/15/19

SHIP TO
DIRECT COMPOUNDING PHARMACY
1850 WHITNEY MESA DR STE 180
HENDERSON NV 89014-2093

BILL TO
Direct Compounding Pharmacy
1850 Whitney Mesa Dr Ste 180
Henderson,NV 89014-2093

T.C.

LOCATION CODE	SHIPPED QTY	EXP. CODE	UNIT SIZE	DESCRIPTION & STRENGTH	ITEM CODE	LINE NO.
D-21-02-34	24	05/19	10ML/VL	TESTOSTERONE CYPI INJ MDV 200MG/M 00143972601 NDC#:0143-9726-01/00143-9726-01 LOT#/Exp:1805099.1 04/30/20 See Terms of Sale for (DSCSA) Compliance Message Details . .GO TO YOUR ONLINE ACCOUNT TO RETRIEVE THIS SDS, 105MK41 - IF YOU CANNOT ACCESS ONLINE OPTIONS OR TO OPT OUT OF ELECTRONIC SDS CALL (800) 472-4346. WELCOME TO E-SDS. BEGINNING TODAY, PAPER SDS WILL NO LONGERBE INCLUDED WITH YOUR ORDER. GO TO YOUR ONLINE ACCOUNT AND CLICK ON SDS LOOK-UP ON THE NAVIGATION PANE. IF YOU DON'T HAVE AN ONLINE ACCOUNT, GO TO WWW.HENRYSCHEIN.COM AND CLICK ONCREATE AN ONLINE ACCOUNT. TO OPT OUT OF OUR ELECTRONIC SDS PROGRAM AND CONTINUE RECEIVING SDS SHEETS WITH YOUR ORDERS PLEASE CALL CUSTOMER SERVICE AT (800) 472-4346. INSOURCE D.C. Dea#: RI0166149 Customer Dea#: FD8137968 Insource Inc. 80 SUMMIT VIEW LANE BASTIAN ,VA 24314	126-2635	1

Donna Nunn
3-25-19

TotQty-24

OFFICE USE ONLY

BATCH# 46673-002

Size:#E2

WT - 1

FREIGHT INSTRUCTIONS UP8 1377

PED

TAB A-6

TAB A-6

B&B Pharmaceuticals Inc.

8591 Prairie Trail Drive - Ste C-600 - Englewood, CO 80112
(800) 499-3100 - www.bbpharm.net

INVOICE

Page 1

Bill-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Ship-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Sell-to Customer No.	C02227	Invoice No.	SPI17511
Bill-to Customer No.	C02227	Order No.	SO18708
DEA License No.	FD8137968	Customer PO No.	
Pharmacy License No.	PH04008	Order Date	4/17/19
B&B DEA License No.	RB0223696	Invoice Date	4/17/19
B&B Wholesaler No.	WH01747	Due Date	5/17/19
Shipment Method	Ground	Payment Terms	NET30
Salesperson	Ian McBride	Payment Method	CHECK

No.	Description	Quantity	Unit of Measure	Unit Price	Lot No.	NDC No.	Amount
700221	Testosterone Non-Micro., USP, CIII	1	100 G	195.00	18L18-BB02-PR00581	63275-8898-06	195.00

Total USD $ **195.00**

** All API's are supplied in BULK RAW powdered form**

Remit Payment to:
B&B Pharmaceuticals Inc.
8591 Prairie Trail Drive - Ste C-600
Englewood, CO 80112

Thank you for your business. B&B Pharmaceuticals strives to provide the best in product quality and customer service.
If you are unsatisfied for any reason please call (800) 499-3100.

B&B Pharmaceuticals Inc.

8591 Prairie Trail Drive - Ste C-600 - Englewood, CO 80112
(800) 499-3100 - www.bbpharm.net

INVOICE

Page 1

Bill-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Ship-to Address
Direct Compounding
Tim Brown
1850 Whitney Mesa Drive
Suite #180
Henderson, NV 89014
United States of America

Sell-to Customer No.	C02227	Invoice No.	SPI17265
Bill-to Customer No.	C02227	Order No.	SO18475
DEA License No.	FD8137968	Customer PO No.	
Pharmacy License No.	PH04006	Order Date	4/1/19
B&B DEA License No.	RB0223696	Invoice Date	4/1/19
B&B Wholesaler No.	WH01747	Due Date	5/1/19
Shipment Method	Ground	Payment Terms	NET30
Salesperson	Ian McBride	Payment Method	CHECK

No.	Description	Quantity	Unit of Measure	Unit Price	Lot No.	NDC No.	Amount
700212	Testosterone Cypionate, USP, CIII	1	100 G	189.00	19A15-BB05-PR00598	63275-8962-05	189.00

Total USD $ **189.00**

** All API's are supplied in BULK RAW powdered form**

Remit Payment to:
B&B Pharmaceuticals Inc.
8591 Prairie Trail Drive - Ste C-600
Englewood, CO 80112

Thank you for your business. B&B Pharmaceuticals strives to provide the best in product quality and customer service.
If you are unsatisfied for any reason please call (800) 499-3100.

EXHIBIT B

EXHIBIT B

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DIRECT COMPOUNDING AND OUTSOURCING, LLC Pharmacy License No. PH04006, SCOT SILBER, RPH, Certificate of Registration No. 08362, MICHAEL THOMAS, PT Certificate of Registration No. PT05905, KRYSTAL HERNANDEZ, PT Certificate of Registration No. PT10671, Respondents.	CASE NOS. 19-070-PH-S 19-070-RPH-S 19-070-PT-A-S 19-070-PT-B-S **DECLARATION OF SCOT M. SILBER, R.Ph. IN SUPPORT OF ANSWER AND NOTICE OF DEFENSE TO NOTICE OF INTENDED ACTION AND ACCUSATION**

I, Scot M. Silber, R.Ph., hereby state and declare as follows:

1. I make this Declaration in support of an Answer and Notice of Defense to Notice of Intended Action and Accusation submitted on behalf of me personally and on behalf of Direct Compounding and Outsourcing, LLC ("Direct Compounding"). I am over the age of eighteen years and competent to testify as to the matters set forth herein. I make this Declaration upon personal knowledge, or upon information and belief where so indicated.

2. I am a licensed and registered pharmacist with the Nevada State Board of Pharmacy pursuant to Certificate of Registration No. 08362. I have practiced pharmacy in the State of Nevada for over thirty-seven years.

3. On April 15, 2019, I met Ellie Gerber – an owner of Direct Compounding – at the business offices for the purposes of interviewing for the position of Pharmacist-in-Charge ("PIC"). I accepted the position of PIC on April 16, 2019, with an official payroll start date of

April 22, 2019 and an actual start date of April 15, 2019. During the week of April 15, 2019 through April 22, 2019, I was onsite at Direct Compounding's facilities for various time periods up to three (3) hours per day, for purposes of setting up my office and reviewing general operations and policies of Direct Compounding.

4. I was present on at least one occasion when Michael Thomas engaged in compounding a pharmaceutical. In addition, I signed-off on one prescription dispensed on April 18, 2019. A true and accurate copy of Direct Compounding's Log of Scripts for the time period April 3, 2019 through April 21, 2019 is attached hereto as Exhibit B-1, which identifies the prescription that was entered into Direct Compounding's computer system on April 17, 2019 and dispensed on April 18, 2019.

5. On April 22, 2019, I engaged a locksmith to change all of the locks to the Direct Compounding facilities. I undertook this project on the advice of Board Staff investigators, who were onsite at the Direct Compounding facilities on this date. In addition, on this same date I worked with Ms. Gerber to change Direct Compounding's alarm system access and contact person to reflect Mr. Silber's authority to act on behalf of the pharmacy. True and accurate copies of invoices and reports related to these two projects are attached hereto as Exhibits B-2 and B-3, respectively.

6. On April 22, 2019, I also prepared an accounting of the controlled substance pharmaceuticals and compounding ingredients in the pharmacy's inventory. I prepared and filed a Change of Managing Pharmacist Inventory with Board Staff on April 22, 2019, identifying the opening-day controlled substances inventory as of this date. A true and accurate copy of this Change of Managing Pharmacist Inventory is attached hereto as Exhibit B-4.

7. To the best of my knowledge, at all times prior to my engagement as PIC, Direct Compounding maintained its inventory of all Schedule II controlled substances in its safe, to which only the PIC had access. Subsequent to my engagement as PIC, Direct Compounding has maintained all of its inventory of Schedule II controlled substances in its safe, to which I have the only access.

8. On April 22, 2019, I also prepared and submitted a Change of Managing Pharmacist Form and Pharmacy Manager's Responsibilities acknowledgement to the Nevada State Board of Pharmacy. A true and accurate copy of the Change of Managing Pharmacist Form and the Pharmacy Manager's Responsibilities acknowledgment are attached hereto as Exhibits B-5 and B-6, respectively.

I declare under penalty of perjury under the laws of the Nevada that the foregoing is true and correct.

Executed this 26th day of May, 2021 in Henderson, Nevada.

R.Ph.

Scot M. Silber, R.Ph.

TAB B-1

TAB B-1

LOG OF SCRIPTS COMBINED PRESCRIPTIONS Schedule: ALL
1 line report
Printed 5/26/2021
Page 1 **Prescriptions filled between 4/4/2019 and 4/21/2019**

Direct Compounding
1650 Whitney Mesa Drive Suite 180
Henderson, NV 89014 Ph. 888-341-0157
NCPDP #2995388 FD8137968

Sorted by: Fill date

Rx number	Date disp	Date written	Patient	Qty and Drug	Doctor	Pharmacist Initials	Re/Rm	Total	Tax	Cost	% profit
C00100035	4/17/2019	3/19/2019	PEARCE, STEVEN	30 OXANDROLONE 25MG CAPSULE	ULEVICH, LYNNE	RPH	2 1	$100.00	$0.00	$38.20	61.80%

1 prescriptions in report

Total price	$100.00
Total price (Insurance pay)	$0.00
Total price (Copay)	$100.00
Total tax	$0.00
Total cost	$38.20
Total profit	$61.80
Average price	$100.00
Average cost	$38.20
% profit margin	61.80%
Average profit per Rx	$61.80
Total price override	($12.50)

1 Pharmacist's signature _____ R.Ph 5/26/21 Date 5/26/2021

My signature on this daily report verifies that the data on this report is complete and correct to the best of my knowledge

Signature 1_____
Signature 2_____
Signature 3_____
Signature 4_____
Signature 5_____
Signature 6_____
Signature 7_____
Signature 8_____

TAB B-2

TAB B-2

SILVERSTATE LOCKSMITH LTD.

№ 6895

800 N. Rainbow Blvd., Suite 148
Las Vegas, NV 89107
702-445-3758
www.Silverstatelocksmith.com

DATE: 4/22/19.

VISA/MASTER CARD/AMERICAN EXPRESS
AUTH CODE: 062417

CUSTOMER DETAILS

NAME Direct Compounding	PHONE 702-217-3866
CREDIT/DEBIT CARD BILLING ADDRESS	SERVICE ADDRESS 1850 Whitney Mesa Dr #180
D.L/I.D NUMBER	ADDITIONAL INFO

IF VEHICLE

YEAR	MAKE	MODEL
TAG	VIN	

PARTS/MATERIALS

QTY	DESCRIPTION	PRICE	AMOUNT
	DUPLICATE KEYS		
	ORIGINAL KEYS		
	DEADBOLT (TYPE)		
	KNOBSET (TYPE)		
	LOCKSET (TYPE)		
	OTHER		

LABOR

QTY	DESCRIPTION	PRICE	AMOUNT
	LABOR TO INSTALL/FIX ABOVE		
6	RE-KEY (CYLINDER COMBINATION CHANGE)	25 00	150 00
	SAFE OPENING/COMBINATION CHANGE		
	EMERGENCY /HOUSE/BUSINESS/VEHICLE/ LOCKOUT SERVICE		
1	SERVICE CALL		65 00
	OTHER -		

Month warranty

SUB TOTAL	215 00
TAX	
TOTAL	215 00

AUTHORIZATION OF SERVICE /INCIDENTAL DAMAGE RELASE/ COMPLETION OF SERVICE

By signing this invoice I hereby certify that I have given the authority to order the service/lock/key/security job as Described above to SilverState Locksmith\technician and I agree to pay fully to the SilverState Locksmith\technician all charges above. I also hereby that I am fully aware of the fact that the estimate Has been provided to me according to the information provided to the locksmith and in the event of SilverState Locksmith/technician discovering additional problems and/or complications additional charges may be applied.

By and through my signature below, I express knowledge and affirm that I have been advised, understand And accept that incidental damage including but not limited to cosmetic and/or mechanical damage to locks, doors Windows and walls can and may occur during inspection, maintenance, repair and/or replacement services. I further acknowledge and agree that the SilverState Locksmith Company and/or the technician shall not be liable in any way for such damage Or associated losses and that I shall remain fully obligated to pay SilverState Locksmith/technician in full prior to or upon completion of the Service(s) as described above

COMPLETION OF SERVICE

By signing this invoice I hereby certify that I was provided the service/lock/key/security job complete to my full satisfaction and Have no further complaints or demands regarding the service.

Signature	Name	date 4/22/19

TAB B-3

TAB B-3

From: Ruth Adams <rutha@asapnv.com>
Date: Mon, Apr 22, 2019 at 3:19 PM
Subject: Fw: alarm system
To: egerber@directcompounding.com <egerber@directcompounding.com>, fsilber@directcompounding.com <fsilber@directcompounding.com>

Hello,

The alarm system is back up and running. I making the changes you requested but I do need them in writing. Please confirm the contact person to be deleted and the name of the person to be added to the account. Code changes are complete.

Your central station number is 855-955-2727

Ruth Adams

aka **The Las Vegas Security Girl** - *I may not be a super hero... But I will protect your home like you had one.*

ASAP Security - ADT Authorized Dealer

3170 Polaris Ave Ste 4

Las Vegas, NV 89102

702-870-8880 Office

702-351-8210 Cell

TAB B-4

TAB B-4

Controlled Inventory

Schedule 3-5 Powders

			Quantity
HCG	3877-2827-01 Meditech	6/4	2 mL
HCG/Triturate 100,000U/gm			9.5gm
Ketamine	63275-9980-05	9-23	10gm
Oxandrolone	62991-2699-03	11-20	17.5gm
Stanozolol	62991-306-[illegible]	9-21	23.35gm
Testosterone Cypionate	63275-9782-05	7-8-20	95gm
Testosterone USP	63276 9988-05	9-18-21	100gm

Schedule 2 Powders

Hydromorphone HCL Powder	63275-2025-4	5/811/23	25gm.5
Morphine Sulfate Powder	63275-1025-4	10/20	25gm5
Fentanyl Citrate Powder	63275-5100-2	2/28/23	25gm 5

Schedule 3-5 Compounded

Stanozolol 25mg Lozenge	Cmpd		36
HCG 1000U/ML 6ML Vial	Cmpd	5/31/19	8

Schedule 3-5 Traditional

Testosterone Cyp. 200mg/ml		62756-016-40	6-19	13
11	11	0143-9926-01	4-20	24

Signature	RPh	Date 4-22-19

Nandrolone USP 63275-9888-05 12/22 100gm

Nandrolone USP 63275 9889-4 12/22 15gm

Oxandrolone caps Cmpd 90 caps

Test cip /grape seed Cmpd 10ml 1ea

Change of Managing RPh - Start of Day Inventory

4-22-19

TAB B-5

TAB B-5

NEVADA STATE BOARD OF PHARMACY

431 W PLUMB LANE – RENO, NV 89509 - (775) 850-1440

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

CHANGE OF MANAGING PHARMACIST FORM

Registration Fee: $50.00

(non-refundable money order or cashier's check only, no cash or business check's)

*This form is only required for pharmacies physically located in Nevada. We only require written notification from an out-of-state pharmacy for a manager change.

General Information

**Nevada Pharmacy Board License #: PH 04006

**(Do not use your RPH, NPI or DEA number. Number begins with a PH, IA, IB)

Pharmacy Name: Direct Compounding and Outsourcing LLC Store #: _____

Address: 1850 Whitney Mesa #180

City: Henderson State: * NV Zip: 89014

Telephone: 702-871-0208 Fax: 702-342-0335

New Managing Pharmacist Name: Scot Silber

License #: 08362 Date Started: 4-22-19

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?....	☐	☒
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?.....	☐	☒
2. Been the subject of an administrative action whether completed or pending in any state?	☒	☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.....	☐	☒

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide documentation:

Board Administrative Action:	**State**		**Case #:**	
	NV	10-17-2012	11-090-BPH-5	
Criminal Action:				

TAB B-6

TAB B-6

PHARMACY MANAGER'S RESPONSIBILITIES

(PHARMACY MANAGER, MUST READ, SIGN AND DATE THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220).

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282; NAC 639.510; NAC 639.473(2).

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NRS 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254(2)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11; NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from the last fill date for original paper prescription). (NRS 639.236; NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268; NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286; NAC 639.487)

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

_____ 4-22-19

Signature of New Managing Pharmacist (no stamps or copies) Date

Board Use Only
Date Received: _____ Amount: _____

Posted 6/30/2011

BOARD'S EXHIBIT "1" STATEMENTS FROM RESPONDENT SCOT SILBER, RPH

4-22-19

TO: Nevada State Board of Pharmacy

From: Scot Silber

1. On April 15, 2019 I met with Ellie Gerber at the Direct Compounding Location.

2. On April 16, 2019 I received an offer of employment - See Attached. I did agree to coming in a few hours each day at NO cost to Direct Compounding.

3. I was aware that Mike Thomas had a key and was coming into the pharmacy along with Krystal Hernandez. I was NOT aware Krystal had a key. I was also not aware the alarm system was not being set. I received the key at 8:30am on 4-22-19.

4. I did come in Monday Apr 15 then Apr 16. On Apr 18th I stayed until Mike Thomas had time to compound. I did sign Rx one Rx on Apr 18th. I was in the pharmacy Each

Page 2

5. During the hours I was present I was reviewing Policy & Procedure both written & verbal. I also was setting up My office.

RRN

4/24/19

To: Nevada State Board of Pharmacy

From: Scot Silber R.Ph. (08362)

Subject: Direct Compounding

Wow what a terrible way to come out of retirement. As noted in my statement I was aware that the techs were in the designated pharmacy area without a pharmacist present. When this first came to my attention I wasn't even scheduled for an interview yet. I was asked to visit the location which I did. I was than scheduled for an interview with Ellie Gerber on April 15, 2019 at the pharmacy. On April 16th I was provided an offer of employment starting on April 22, 2019. I did agree to come in to the pharmacy a few hours each day, for free, to get my personal items situated so I could start working Monday.

Frankly on my first visit I had no clue of the organizational structure or what was going on and it wasn't my position to ask. On my subsequent visits I did know and in retrospect I should have said something to both the techs and owners even if it wasn't my place to do so.

Going forward I have learned a valuable lesion "see something say something". I am truly sorry for not doing more knowing it was clearly wrong. Knowing this was not correct I do plan on spending a good portion of my upcoming CE on Pharmacy law and ethics.



BOARD'S EXHIBIT "2" STATEMENTS FROM ELIE GERBER ON BEHALF OF RESPONDENT DIRECT COMPOUNDING AND OUTSOURCING, LLC

April 24, 2019

To: Kenneth Scheuber and Members of the Nevada Board Of Pharmacy
Re: Direct Compounding and Outsourcing, LLC
PH04006

To Whom it May Concern,

I would like to start by giving a little history to my position in Direct Compounding as well as my previous experience in the pharmacy industry. I worked for a California based retail pharmacy for 6 years but only as a Business Operation Manager. My job was remotely located out of my home office and I was never on site at any of the pharmacy locations. My job duties included helping facilitate buildout of locations, infrastructure (IT, Alarm systems, Phone), gathering of employee paperwork for new hires, reconciliation of books, sales analysis and projections at each of the locations. My position with Direct Compounding is the same with the exception of my presence at the actual facility to help communication between the team and T[redacted]B[redacted](pic) prior to opening. Throughout the buildout of this company communication between Mr. B[redacted] management, and the support staff has been a major challenge. Discussions often ended in a volatile way with Mr. B[redacted] throwing a tantrum and walking out. The reason this is important is because much of what was happening at the location was kept a secret and when asked about daily activities little to no response would be provided by Mr. B[redacted] Mr. B[redacted] even went so far to tell the support staff, Michael Thomas and Krystal Hernandez, that they did not have to respond to managements requests for information and that he was unilaterally responsible for all decisions. To my knowledge Mr. B[redacted] would leave throughout the day to go to clinics to do "marketing" and would leave the techs at the site, however, this was prior to us being open for business and I am unaware of what products were in the facility. My last visit to the facility while Mr. B[redacted] was employed was March 5th-7th. I was there to meet with our IT consultant to finish the configuration of the system for e-scripts and final adjustments prior to opening. I called a meeting with Mr.B[redacted] to ask if he had set up for a clinic to send us a test script so we could ensure that the system was working properly and was quickly met with anger and yelling about how he can't make miracles happen and how we were out to get him and then he stormed out. For the next two days Mr.B[redacted] gave me the silent treatment, and when he did speak to either of the techs it was directions on how they need to cease communication with management and harassed them about how they were all conspiring against him. At that point we realized we had unreconcilable differences and the environment for all employees had turned toxic. We began the search for a new PIC candidate. The next two weeks Mr. B[redacted] spent the majority of his time on the back office computer searching for local restaurants and listening to his conspiracy theory podcasts as well as updating his resume.

On April 4th, 2019 Mr. B[redacted] was terminated. According to the staff they all left the facility together with Mr.B[redacted] while he was making hasty threats about them getting fired as

well. In addition he made remarked about making sure he let the board know- I had no idea what that meant as I had already emailed the board about what process needed to happen to change our PIC. On April 4th I emailed pharmacy@pharmacy.nv.gov an email asking what I needed to do to update our pic along with two other questions. Not only did I not get an email with a response back I didn't even receive acknowledgment of receipt of my email from anyone at the BOP. Out of concern for Mr. B[redacted] coming back to the facility the other owner wanted the locksmith called out. Michael Thomas agreed to meet the locksmith at the facility to have the building re-keyed but I was never told by him or anyone else that he couldn't do that. The only text I received was one asking for a form of payment for the locksmith. On April 4th I also emailed Mr. Thomas to tell him that I hadn't heard back from the BOP regarding doing a PIC change and he let me know he could follow up and see if he could get the information needed. April 5th Mr. Thomas said that he was going to be able to meet two potential pharmacists at the facility to give them a tour. The pharmacist didn't call so there was no meeting to my knowledge. On April 10th I texted Mr. Thomas to ask if he was onsite and said he was not, and that Ms. Hernandez was sick. I asked him how many hours he thought we would work on pharmacy stuff that day and I would add the hours to his timecard for him. I also sent him directions on how to access the timecard system from his computer at home. I emailed the HR company that does our payroll that they would see remote logins from both staff members since they would be working remotely.

On April 12th-15th I was coming to town for my daughter's gymnastics meet. I scheduled a meeting to meet with Scot Silber at the pharmacy on April 15th at 9:30 am as a potential PIC. I texted Mr. Thomas on Sunday the 14th to ask if my old key that used to work for the side door that led to back staircase and my office still worked. He replied "Your key does not work. No alarm and that he was planning to be there by 9." Ms. Hernandez replied that she would be there at 9 as well. I let them know that I had to go to the bank first but would be there to meet with Scot. I used the side parking lot (east) parking lot and was knocking on that door under the impression that we were working out of that side of the office. When no one answered I texted Krystal to let her know I was there, and she came around and got me and we walked into the front door of the building. Mr. Silber showed up slightly after and we proceeded to meet in the front entryway and talk about his potential employment. I went upstairs to my office to retrieve a bunch of files needed for taxes and then gathered the mail and left for my trip home to California.

When Mr. Silber called me on Monday April 22nd to let me know that the BOP found the alarm not to be working, I was surprised. Mr. B[redacted] was given access to have control of passwords and logins since he told me that was how it had to be. Since I was paying the bills and hadn't heard any word otherwise I assumed the alarm system was being used and that he was setting it. ASAP security not only said it hadn't been set but someone had unplugged it multiple times. The only one that had access to do that would be Mr. B[redacted] but have no idea why he would do that. I also had no knowledge of drug storage at the facility, my understanding was that all controlled substances were kept in the locked safe that Mr. B[redacted] exclusively had the code for. If you would like copies of the mentioned text messages and emails above I would be happy to provide them.

BOARD'S EXHIBIT "3" STATEMENTS FROM RESPONDENT MICHAEL THOMAS, PT

To the best of my knowledge these are the issues to be addressed:

1. I Acquired a key after locksmith rekeyed on 4-4-19 after T[redacted] B[redacted] was let go from employment.
2. The pharmacy was opened and closed on several days without a pharmacist. No patients had access to the pharmacy at this time.
3. Scot Silber was at the pharmacy on 4-15, 4-16, 4-17, 4-18. Stayed several hours each of those days.
4. Only compounded product that was made from 4-4-19 to 4-22-19 was on 4-18-19 while Scot was here.
5. Krystal's Hernandez schedule was similar to my schedule. Krystal does have a key.
6. 1 item was received from Medisca on 4-17-19. Stearic Acid powder. This occurred while Scot was here.
7. The alarm system has not been actively set since 4-4-19. I do not have codes for this system.
8. I gave my key to Scot Silber first thing the morning of 4-22-19.
9. Ellie Gerber was aware that both Krystal and I were in the pharmacy at times from 4-4-19 to 4-22-19 without a pharmacist.

Michael Thomas

Date: 4-22-19

I have come to understand that I have made mistakes in my pharmacy career. I have let myself compromise my values and in doing so I have jeopardized my own livelihood and principals.

The last year of my life has been one of the hardest I have dealt with. I was working for a company that I thought was a good fit for me and my skills and I had been there for several years. The ownership of that business and my ideas while not always the same I thought we were on a path to better things. Then there was an inspection by the fda and a lot of my ideas were given merit. This inspection was the most stressful 2 weeks I had ever dealt with in my career. However I thought getting through it and refocusing would be the answer. Unfortunately, the ownership of the company decided that instead of moving to better the facilities and practices they would shut down the sterile lab and end my employment. This left me without work and unsure if I wanted to work in a pharmacy again. At this point in my life I had never been unemployed. I have worked in some form or another since age 15. The next week my father had a heart attack and went through a quintuple bypass. It took me some time to regain my composure. I finally found a position with what I believed to be a company that wanted to do great things and focus on doing things properly. It started as a great new venture. Starting a new business with the intent on creating something I could be proud of.

As time progressed, I became aware that things were not running smoothly but I considered it part of the process with starting a new business. Then our pharmacist was let go by upper management and we were without a licensed pharmacist. I was informed by Ellie Gerber (an owner of the company) that they intended to keep the staff of myself and our other technician Krystal Hernandez. I was asked to meet with a locksmith and have the locks changed on the pharmacy. I did not give it enough thought at the time and agreed to do this. This was my first mistake. I now had keys to a pharmacy.

After speaking with Ellie she informed me that Krystal and I could go in to work and make sure that any paperwork that needed doing or any requests be rerouted so that if anyone needed anything we could point them in the right direction as we could not fill any prescriptions. I agreed to do this. Now I have worked in a pharmacy without the supervision of a pharmacist. This was my second mistake.

I wish I had made different decisions. I had been out of work for some time before this position and monetarily I must support myself. I had the vision of being a part of a proper pharmacy with great intentions. I was trying to preserve that vision. In trying to support myself and preserve my vision, I did exactly the opposite and made decisions that may completely compromise my ability to attain my goals.

Thank you,

Michael Thomas

BOARD'S EXHIBIT "4" STATEMENTS FROM RESPONDENT KRYSTAL HERNANDEZ, PT

To whom it may concern,

The following are issues requested of me to be addressed:

~ All the doors were rekeyed on 04/04/19 the day T[redacted] B[redacted] was fired, but I did not get a new key until 04/08/19.
~ I had a key previously when T[redacted] B[redacted] was still the pharmacist, but this key only gave me access to the office, bathrooms, storage closet, and upstairs. I did not have access to any medications what so ever.
~ Scott worked 04/15, 04/16, 04/17, 04/18. He was also here 04/12 because he wanted to see the pharmacy.
~ The only day compounding was done was 04/18 when Scott was here. The physical compounding was done by Mike, then checked by Scott.
~ We did receive one delivery from Medisca on 04/17 when Scott was here.
~ I never activated or deactivated any alarm, nor did I ever have any codes for the alarm dates 4/04 – 04/23.
~ Ellie Gerber knew we were at the pharmacy without a pharmacist present.
~ I gave Scott my keys 04/23/19 when we came into the pharmacy.

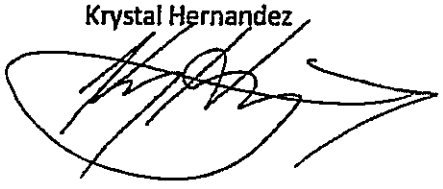
Date: 04/23/19 Signature: [redacted]

I want to take this time to express my deepest regret and apologize to those I have let down. It was never my intention to bring so much shame and disappointment to those that love me or to the people that helped get me to where I am in my career today. I want you to know that I understand it was my own actions that led me here. I will not place this blame on anyone except myself, just please know my heart is heavy with remorse. I let the fear of losing my job and income completely blind me on the possibility of losing my career. I wanted to write this to give you a better understanding of me as well as my thoughts and feelings on the issue at hand. Also, to explain what I have learned and what I plan to do differently in the future if given the opportunity.

Since I was child, I knew I wanted a career helping others. Finding myself a young, single mother I jumped right into a pharmacy technician program after doing some research on different career paths. I was hired right out of school where I finished my last internship at. It was at this pharmacy I learned just how important a technician's role is in a patient's life. Most days I would find myself aggressively pursuing an insurance to get a chemo medication covered or helping a patient find copay assistance. I love what I do for the simple fact that I can help others get what they need to maintain or help improve their health. After the unfortunate events that took place, I find myself very much lost in fear. Fear of losing something I love and worked so hard for, fear of losing the only means I have to provide for my daughter and myself, and fear of not being able to right my wrongs. These thoughts weigh on me heavily, especially at night. I am up most nights now wondering why I let myself make such an idiotic mistake, questioning how I could ever jeopardize my livelihood like this, and wondering if I just ruined my daughter's life right along with mine. I have always been the technician who brings up the things that need to be fixed at a pharmacy, not one to create the issue. If I had the chance to have one do over in life, there is no doubt that this would be it. I would instead suffer the loss of pay for how ever long it took to find a new pharmacist than to run the risk of losing my career that I feel is my calling. If I am ever put in a situation like this again, I can promise you that I would make the right choice as well as report any unlawful requests of me to the board. It is very important for me to make you aware that although I was at the pharmacy, the door remained locked and the pharmacy closed. I did not touch any medication and no prescription was processed as the cameras and computers can verify. With that being said, my actions were still wrong. I should have never been there or accepted the key once I realized it opened all the doors. I have never in my life carried so much guilt, the kind of guilt that makes you physically ill and leaves a permanent lump in your throat. It comes from knowing that I let people down tremendously, including myself. I could never put into words just how sorry I truly am.

I never in my wildest dreams thought that I would be in this position. Being here now I want to say I agree that my actions leading up to this point were wrong and should have never happened. I have never been in trouble with the board before and I can promise you that you will never hear my name involved with anything like this again. I have been praying night and day that you can see how remorseful I truly am and can see my true character. Please give me the opportunity to prove to you that I have learned from this. Let me restore the faith in those that I have let down. I beg that you allow me to continue to provide for my daughter with the career choice I chose ten years ago and still love just as much today. I appreciate you taking the time to read this, thank you.

Best Regards,
Krystal Hernandez



BOARD'S EXHIBIT "5" TIMESHEETS FOR MICHAEL THOMAS, PT AND KRYSTAL HERNANDEZ, PT

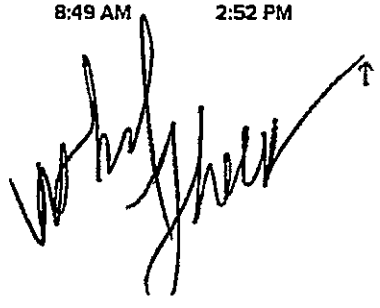
Your TimeCard

Pay Period:

04/08/2019 thru 04/21/2019

Print PDF

Date	TOTAL	REG	OT1	OT2	OT3	IN	OUT
04/08/2019	6.02	6.02	0.00	0.00	0.00	8:48 AM	2:49 PM
In @ 8:48 AM		Out @ 2:49 PM		Total: 6.02 hours			
04/09/2019	5.93	5.93	0.00	0.00	0.00	8:48 AM	2:44 PM
In @ 8:48 AM		Out @ 2:44 PM		Total: 5.93 hours			
04/11/2019	5.97	5.97	0.00	0.00	0.00	8:51 AM	2:49 PM
In @ 8:51 AM		Out @ 2:49 PM		Total: 5.97 hours			
04/12/2019	6.08	6.08	0.00	0.00	0.00	8:44 AM	2:49 PM
In @ 8:44 AM		Out @ 2:49 PM		Total: 6.08 hours			
04/15/2019	6.18	6.18	0.00	0.00	0.00	8:39 AM	2:50 PM
In @ 8:39 AM		Out @ 2:50 PM		Total: 6.18 hours			
04/16/2019	6.10	6.10	0.00	0.00	0.00	8:50 AM	2:56 PM
In @ 8:50 AM		Out @ 2:56 PM		Total: 6.1 hours			
04/17/2019	6.05	6.05	0.00	0.00	0.00	8:49 AM	2:52 PM
TOTALS	48.96	48.96	0.00	0.00	0.00		



Date	TOTAL	REG	OT1	OT2	OT3	IN	OUT
In @ 8:49 AM		Out @ 2:52 PM		Total: 6.05 hours			
04/18/2019	6.13	6.13	0.00	0.00	0.00	8:47 AM	2:55 PM
In @ 8:47 AM		Out @ 2:55 PM		Total: 6.13 hours			
04/19/2019	0.50	0.50	0.00	0.00	0.00	8:57 AM	9:27 AM
In @ 8:57 AM		Out @ 9:27 AM		Total: 0.5 hours			
TOTALS	48.96	48.96	0.00	0.00	0.00		

on the clock

is available for...

Web Browser — Windows/Mac
Tablet — Android/Apple
Mobile App — Android/Apple
Google Play — Android App
Apple — Apple App

Contact Us

Customer Reviews
Customer Success Stories
Contact Us
Call (Phone)
(888)-753-5999
22800 Hall Road, Clinton Township, MI 48036

Product

Online Time Clock
Mobile Time Clock
GPS / Fingerprint
Time Off Tracking (PTO)
Shift Scheduling
Payroll Integration

Company

About Us
Careers
Meet Us
Blog
Philanthropy
Partners

Support

Getting Started
Help Topics
FAQ
Helpful Videos
Uptime Reports
Free Templates

Resources

Calculators & Converters
Federal Holidays
2018 State Minimum Wage
Employee Overtime Rules
Find Your Time Zone
Software Downloads

Join us on Social Media

We'd love to hear from you

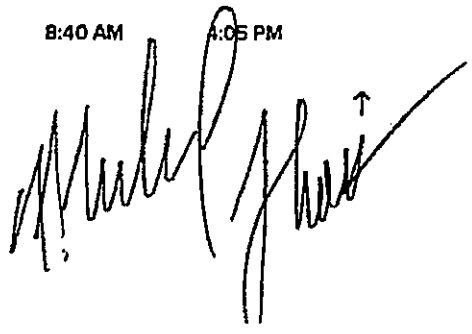
Your TimeCard

Pay Period:

03/25/2019 thru 04/07/2019

Print PDF

Date	TOTAL	REG	OT1	OT2	OT3	IN	OUT
03/26/2019	3.23	3.23	0.00	0.00	0.00	8:38 AM	11:52 AM
In @ 8:38 AM		Out @ 11:52 AM		Total: 3.23 hours			
03/27/2019	6.96	6.96	0.00	0.00	0.00	9:14 AM	4:44 PM
In @ 9:14 AM		Out @ 2:01 PM		Total: 4.78 hours			
In @ 2:33 PM		Out @ 4:44 PM		Total: 2.18 hours			
03/28/2019	6.77	6.77	0.00	0.00	0.00	8:47 AM	4:07 PM
In @ 8:47 AM		Out @ 1:15 PM		Total: 4.47 hours			
In @ 1:49 PM		Out @ 4:07 PM		Total: 2.3 hours			
03/29/2019	7.45	7.45	0.00	0.00	0.00	8:33 AM	4:32 PM
In @ 8:33 AM		Out @ 12:26 PM		Total: 3.88 hours			
In @ 12:58 PM		Out @ 4:32 PM		Total: 3.57 hours			
04/01/2019	7.69	7.69	0.00	0.00	0.00	8:37 AM	4:54 PM
In @ 8:37 AM		Out @ 1:38 PM		Total: 5.02 hours			
In @ 2:14 PM		Out @ 4:54 PM		Total: 2.67 hours			
04/02/2019	6.85	6.85	0.00	0.00	0.00	8:40 AM	4:05 PM
TOTALS	46.81	46.81	0.00	0.00	0.00		



Date	TOTAL	REG	OT1	OT2	OT3	IN	OUT
In @ 8:40 AM		Out @ 1:36 PM		Total: 4.93 hours			
In @ 2:10 PM		Out @ 4:05 PM		Total: 1.92 hours			
04/03/2019	6.36	6.36	0.00	0.00	0.00	8:46 AM	3:59 PM
In @ 8:46 AM		Out @ 1:06 PM		Total: 4.33 hours			
In @ 1:57 PM		Out @ 3:59 PM		Total: 2.03 hours			
04/04/2019	1.50	1.50	0.00	0.00	0.00	8:46 AM	10:16 AM
In @ 8:46 AM		Out @ 10:16 AM		Total: 1.5 hours			
TOTALS	46.81	46.81	0.00	0.00	0.00		

on the clock

is available for...

Web Browser
Windows/Mac

Tablet
Android/Apple

Mobile App
Android/Apple

Google Play
Android App

Apple
Apple App

Contact Us

Customer Reviews

Customer Success Stories

Contact Us

Call (Phone)

(888)-753-5999

22800 Hall Road, Clinton Township, MI 48036

Product

Online Time Clock

Mobile Time Clock

GPS / Fingerprint

Time Off Tracking (PTO)

Shift Scheduling

Payroll Integration

Company

About Us

Careers

Meet Us

Blog

Philanthropy

Partners

Support

Getting Started

Help Topics

FAQ

Helpful Videos

Uptime Reports

Free Templates

Resources

Calculators & Converters

Federal Holidays

2018 State Minimum Wage

Employee Overtime Rules

Find Your Time Zone

Software Downloads

Date	TOTAL	REG	IN	OUT
04/08/2019	5.73	5.73	9:12 AM	2:56 PM
In @ 9:12 AM	Out @ 2:56 PM	Total: 5.73 hours		
04/09/2019	6.39	6.39	8:14 AM	3:04 PM
In @ 8:14 AM	Out @ 1:15 PM	Total: 5.02 hours		
In @ 1:42 PM	Out @ 3:04 PM	Total: 1.37 hours		
04/11/2019	6.70	6.70	7:43 AM	2:53 PM
In @ 7:43 AM	Out @ 12:41 PM	Total: 4.97 hours		
In @ 1:09 PM	Out @ 2:53 PM	Total: 1.73 hours		
04/12/2019	6.38	6.38	8:03 AM	2:50 PM
In @ 8:03 AM	Out @ 12:05 PM	Total: 4.03 hours		
In @ 12:29 PM	Out @ 2:50 PM	Total: 2.35 hours		
04/15/2019	6.00	6.00	8:27 AM	2:55 PM
In @ 8:27 AM	Out @ 1:00 PM	Total: 4.55 hours		
In @ 1:28 PM	Out @ 2:55 PM	Total: 1.45 hours		
04/16/2019	6.25	6.25	8:13 AM	2:56 PM
In @ 8:13 AM	Out @ 1:27 PM	Total: 5.23 hours		
In @ 1:55 PM	Out @ 2:56 PM	Total: 1.02 hours		
04/17/2019	6.54	6.54	8:09 AM	3:09 PM
In @ 8:09 AM	Out @ 1:07 PM	Total: 4.97 hours		
In @ 1:35 PM	Out @ 3:09 PM	Total: 1.57 hours		
04/18/2019	6.19	6.19	8:20 AM	2:56 PM
In @ 8:20 AM	Out @ 1:15 PM	Total: 4.92 hours		
In @ 1:40 PM	Out @ 2:56 PM	Total: 1.27 hours		

Krystal Hernandez 4/23/19

Date	TOTAL	REG	IN	OUT
03/25/2019	7.39	7.39	8:13 AM	4:03 PM
In @ 8:13 AM	Out @ 1:35 PM	Total: 5.37 hours		
In @ 2:02 PM	Out @ 4:03 PM	Total: 2.02 hours		
03/26/2019	7.95	7.95	8:07 AM	4:32 PM
In @ 8:07 AM	Out @ 1:20 PM	Total: 5.22 hours		
In @ 1:48 PM	Out @ 4:32 PM	Total: 2.73 hours		
03/27/2019	7.70	7.70	8:13 AM	4:22 PM
In @ 8:13 AM	Out @ 12:47 PM	Total: 4.57 hours		
In @ 1:14 PM	Out @ 4:22 PM	Total: 3.13 hours		
03/28/2019	6.48	6.48	8:21 AM	2:50 PM
In @ 8:21 AM	Out @ 2:50 PM	Total: 6.48 hours		
03/29/2019	7.11	7.11	8:14 AM	3:52 PM
In @ 8:14 AM	Out @ 1:22 PM	Total: 5.13 hours		
In @ 1:53 PM	Out @ 3:52 PM	Total: 1.98 hours		
04/01/2019	7.71	7.71	8:18 AM	4:30 PM
In @ 8:18 AM	Out @ 1:59 PM	Total: 5.68 hours		
In @ 2:28 PM	Out @ 4:30 PM	Total: 2.03 hours		
04/02/2019	7.83	7.83	8:20 AM	4:40 PM
In @ 8:20 AM	Out @ 1:10 PM	Total: 4.83 hours		
In @ 1:40 PM	Out @ 4:40 PM	Total: 3 hours		
04/04/2019	2.15	2.15	8:09 AM	10:18 AM
In @ 8:09 AM	Out @ 10:18 AM	Total: 2.15 hours		

Krystal Hernandez 4/23/19

BOARD'S EXHIBIT "6" RESPONDENT DIRECT'S LOGGED FORMULA WORKSHEET SHOWING PHARMACIST SILBER ON APRIL 18, 2019

Logged Formula Worksheet (standard)

4/18/2019 10:28:44 AM
Page 1

Direct Compounding
1850 Whitney Mesa Drive Suite 180
Henderson, NV 89014 Ph. 702-877-0703

OXANDROLONE 25MG CAPSULE

Tall Man:

Flavor:
Description: WHITE TO OFF WHI[redacted]R IN A CAPSULE
Quantity made: 100 CAP
Batch yield: 100.000
Qty remaining: 100.000

NIOSH Hazard ☑
Schedule: L HRTCAP
Active ☑
Formula ID: 377
Log ID: 38
PCCA ID:
Route of admin: ORAL

Date made: 4/18/2019
Lot number: 04182019@3
Beyond use date: October 15, 2019 10:24 AM
180 days after compounding date
Pharmacist: SCOT SILBER
Technician: MICHAEL THOMAS
NDC1:
Packaging:
Equipment:

Labeling:
Stability information:
Storage information:

Pricing calculations from the log
Estimated price $3,767.13 as of 3/20/2019
Time to make: 0

Ingredients	NIOSH Hazard	Sch.	Quantity used	QS (Balance)
1 OXANDROLONE POWDER Lot #: 1902040002 Chemical Code: Purity: Balance: Percent off: 0.200% (over weight). 2.505 g	☐		2.5 GM Mfg: LETCO Exp. date: 11/30/2020 Volume: Potency: QS amount: Bar code checked: ☑ Each CAP contains 0.025 GM or 2.5% NDC: 62991269903	☐ 2.505 g Whlsr: LETCO AWP: $3,750.00 ChemInvID: 125
2 METHYLCELLULOSE 4000CPS USP POWDER Lot #: 1812130024 Chemical Code: Purity: Balance: Percent off: 0.043% (under weight). 18.802 g	☐		18.81 GM Mfg: LETCO Exp. date: 10/25/2019 Volume: Potency: QS amount: Bar code checked: ☑ Each CAP contains 0.188 GM or 18.8% NDC: 62991282201	☐ 18.802 Whlsr: LETCO AWP: $12.13 ChemInvID: 85
3 CAPSULE WHITE/WHITE #1 SUPPLY Lot #: 159731/E Chemical Code: Purity: Balance:	☐		100 EA Mfg: MEDISCA Exp. date: 10/31/2021 Volume: Potency: QS amount: Bar code checked: ☑ Each CAP contains 1 EA or 100% NDC: 38779316002	☐ Whlsr: MEDISCA AWP: $5.00 ChemInvID: 121

Log Instructions & Notes

New Log Originally made as: 100 OXANDROLONE 25MG CAPSULE Formula ID: 377
Calculated lot number: 04182019@3 Beyond use date: 10/15/2019
FORMULA INSTRUCTIONS:
NOTE: Oxandrolone packing stat = 200mg in a size #1 capsule.
NOTE: Methylcellulose packing stat = 215mg in a size #1 capsule.
NOTE: 25mg/200 = 0.125 or 12.5% is Oxandrolone .
NOTE: 12.5% - 100% = 87.5% is Methylcellulose or 188.125mg.

1. Weigh Oxandrolone into a weigh canoe.

2. Weigh Methylcellulose into a weigh canoe.

3. Mix both powders together in a powder blender. Ensure sufficient time is allowed for a complete mixture.

4. Fill into Size #1 capsules using the capsule press.

Date entered: 4/18/2019 10:24:36 AM Last modified: 4/18/2019 10:28:39 AM by: MICHAEL THOMAS
Checked by: _____ Date: 4/19/19

Direct Compounding
1850 Whitney Mesa Drive Suite 180
Henderson, NV 89014 Ph. 702-877-0703

TEST CYP (GRAPESEED) (6ML VIAL) 200MG/ML INJECTABLE

Tall Man:

NIOSH Hazard ☑
Active ☑

Flavor:
Description: OFF WHITE TO YELLOW OIL BASED SOLUTION
Schedule: 3 INJ
Formula ID: 355
Log ID: 36

Quantity made: 30 ML
Batch yield: 30.000
Qty remaining: 30.000
PCCA ID:
Route of admin: SUB-Q

Date made: 4/18/2019
Lot number: 04182019@2
Beyond use date: May 2, 2019 10:03 AM
14 days after compounding date
Pharmacist: SCOT SILBER
Technician: MICHAEL THOMAS
NDC1: 63275998204
Packaging:
Equipment:

Pricing calculations from the log
Estimated price $461.34 as of 3/14/2019
Time to make: 0

Labeling:
Stability information:
Storage information:

Ingredients	NIOSH Hazard	Sch.	Quantity used	QS	(Balance)
1 TESTOSTERONE CYPIONATE POWDER Lot #: 17J27-BB01-PR00351 Mfg: B&B Chemical Code: Volume: Potency: Purity: Balance Percent off: 1.000% (under weight). 0.990 g	☒	3	1 GM Exp. date: 9/30/2019 QS amount:	☐	0.990 g Whlsr: B&B AWP: $71.96 Bar code checked: ☑ Each ML contains 0.0333 GM or 3.33% NDC: 63275998204 CheminvID: 89
2 BENZYL ALCOHOL LIQUID Lot #: 149504/A Mfg: MEDISCA Chemical Code Volume: Potency: Purity: Balance:	☐		9 ML Exp. date: 3/30/2020 QS amount: 9.00	☐	Whlsr: MEDISCA AWP: $2.83 Bar code checked ☑ Each ML contains 0.3 ML or 30% NDC: 38779102908 CheminvID: 112
3 ETHANOL (ETHYL ALCOHOL) LIQUID Lot #: 156353/A Mfg: MEDISCA Chemical Code Volume: Potency: Purity Balance	☐		1.5 ML Exp. date: 8/31/2021 QS amount: 1.50	☐	Whlsr: MEDISCA AWP: $0.54 Bar code checked: ☑ Each ML contains 0.05 ML or 5% NDC: 38779061601 CheminvID: 77
4 GRAPESEED OIL OIL Lot #: 156673/B Mfg: MEDISCA Chemical Code: Volume: Potency: Purity: Balance	☐		30 ML Exp. date: 8/31/2020 QS amount: 20.03	☒	Whlsr: MEDISCA AWP: $21.09 Bar code checked: ☑ Each ML contains 1 ML or 100% NDC: 38779208908 CheminvID: 101
5 TESTOSTERONE CYPIONATE POWDER Lot #: 19A15-BB05-PR00596 Mfg: BB Chemical Code: Volume: Potency: Purity: Balance: Percent off: 0.560% (over weight). 5.028 g	☒	3	5 GM Exp. date: 7/8/2020 QS amount:	☐	5.028 Whlsr: BB AWP: $359.80 Bar code checked: ☑ Each ML contains 0.167 GM or 16.7% NDC: 63275998205 CheminvID: 129

Log Instructions & Notes

New Log Originally made as: 30 TEST CYP (GRAPESEED) (6ML VIAL) 200MG/ML INJECTABLE Formula ID: 355
Calculated lot number: 04182019@2 Beyond use date: 5/2/2019
FORMULA INSTRUCTIONS:
NOTE: If stored at room temperature a maximum beyond use date of 14 days for terminally sterilized oil based products pending further testing.
NOTE: The use of an ISO 5 environment, prepared glassware, instruments, and proper aseptic technique shall be utilized when compounding sterile products.
NOTE: This preparation is terminally sterilized using the autoclave. Document all forms necessary.
NOTE: Personal Protective Equipment shall be used in the assembly of this formulation as it contains hormones that are on the NIOSH list.

Date entered: 4/18/2019 10:07:15 AM Last modified: 4/18/2019 10:10:43 AM by: MICHAEL THOMAS
Checked by: _____ Date: 4/19/19

Direct Compounding
1850 Whitney Mesa Drive Suite 180
Henderson, NV 89014 Ph, 702-877-0703

TEST CYP (GRAPESEED) (6ML VIAL) 200MG/ML INJECTABLE

Tall Man:

NIOSH Hazard ☑
Active ☑

Flavor:
Description: OFF WHITE TO YELLOW OIL BASED SOLUTION
Schedule: 3 INJ
Formula ID: 355
Log ID: 36

Quantity made: 30 ML
Batch yield: 30.000
Qty remaining: 30.000
PCCA ID:
Route of admin: SUB-Q

1. Weigh Testosterone Cyp. Powder and transfer to a beaker large enough to hold the entire formulation.

2. Add Ethanol and Benzyl Alcohol to the beaker as well. This helps wet the powders and starts the dissolution process.

3. Add 30% of the Grapeseed Oil to the beaker and allow the mixture to mix until all the powder is dissolved.

4. Transfer to a precise measuring container and add enough grapeseed oil to meet the final quantity to be made.

5. Transfer back to the mixing container and allow to mix to ensure an even mixture.

6. Transfer 6ml into pre-sterilized 5ml vials.

7. Seal and crimp the vial.

8. Place sealed vials into the autoclave and run the autoclave at 121C for 20 minutes. Document appropriately.

9. Once the vials have cooled from the autoclave label appropriately.

Sterile Information

Sterile item: ☑ Sterility checked: ☐ Date checked: Checked by: (for quality assurance)
Lab used:
Particulate testing:
Pyrogen testing results:
Endotoxin testing results:
In house lot numbers for testing purposes:
General testing results:
Sterility notes:
Method used:
Potency testing: ☐
Quarantine date:
Release date:
Isotonicity:
pH:

Date entered: 4/18/2019 10:03:15 AM Last modified: 4/18/2019 10:10:43 AM by: MICHAEL THOMAS
Checked by: _____ Date: ___/___/_____

DIRECT compounding

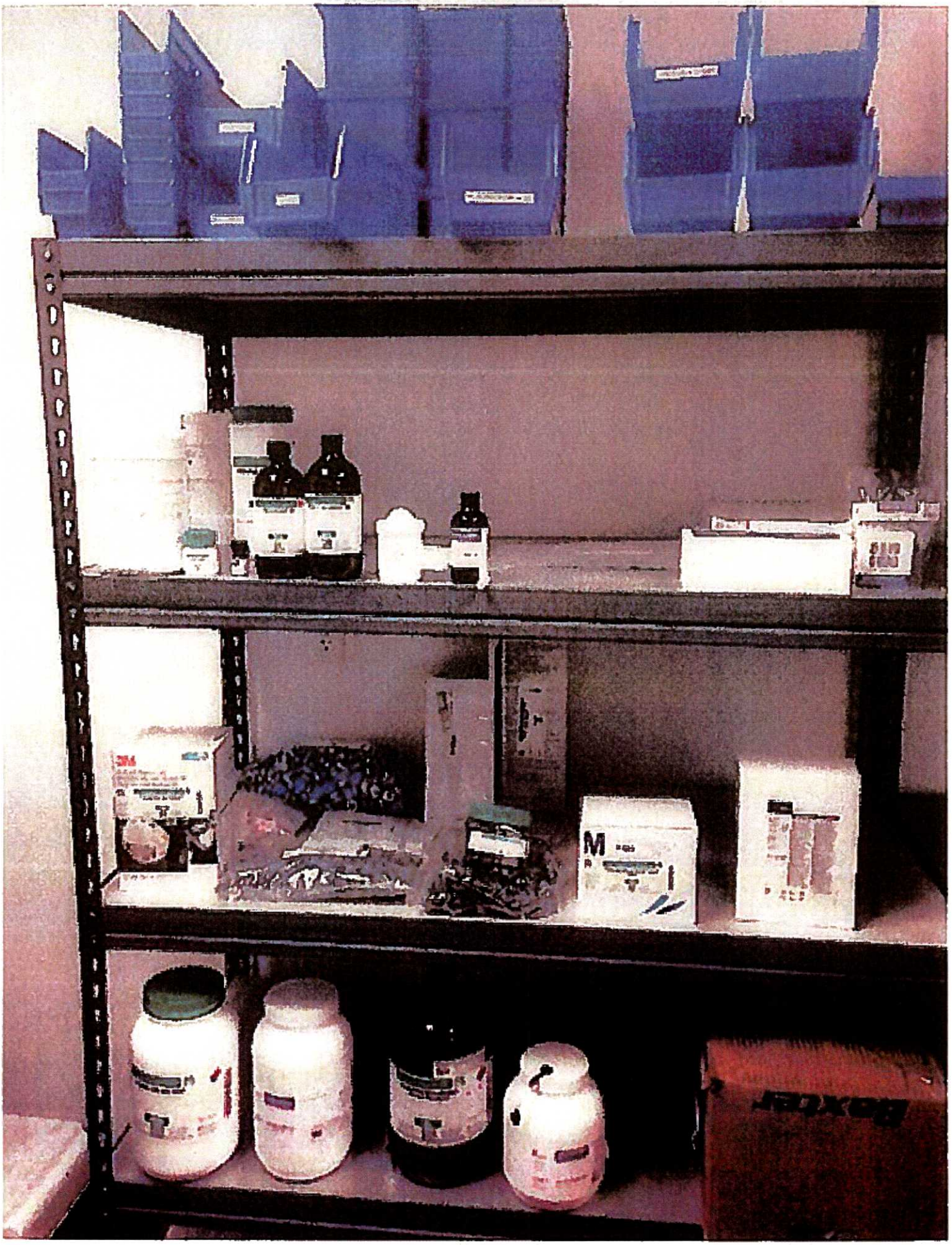
Minimum temperature requirement for sterilization is 121C(250F). The minimum time interval is 20 minutes. A pressure of 15 PSI is also needed to ensure proper sterilization. Increased time or temperature may be needed dependent on the size of the load.

Autoclave Make: Tuttnauer		Location: Sterile Prep	
Autoclave Model: E29		Inservice Date: 3-5-19	

Date	Contents	Temp	Deration Of Cycle	Pressure	Chemical Indicator Result (Pass/Fail)	Biological Indicator Used? (Y/N)	Operator Initials	Comments
3-5-19	5mL Amber Vials 20mm Stoppers	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-6-19
3-5-19	3mL Vials	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-6-19
3-5-19	5mL Amber Vials 30mL Amber Vials	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-6-19
3-5-19	5mL Amber Vials	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-6-19
3-15-19	20mm Crimper 13mm Crimper	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-18-19
3-18-19	10x5mL Vials Nandrolone 200mg/mL	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-19-19
3-18-19	10x10mL Vials Testcyp 200mg/mL	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 3-19-19
4-1-19	10x10mL Vials Testcyp 200mg/mL	250C	25 min	17	Pass	Y	[illegible]	BioIndicator Pass 4-2-19
4-18-19	5x6mL Vials Testcyp 200mg/mL	250C	25 min	17		Y	[illegible]	BioIndicator

BOARD'S EXHIBIT "7" PHOTOGRAPHS OF DIRECT'S PHARMACY SHELVES AND DANGEROUS DRUGS AND CONTROLLED SUBSTANCES PRESENT


KIMTECH

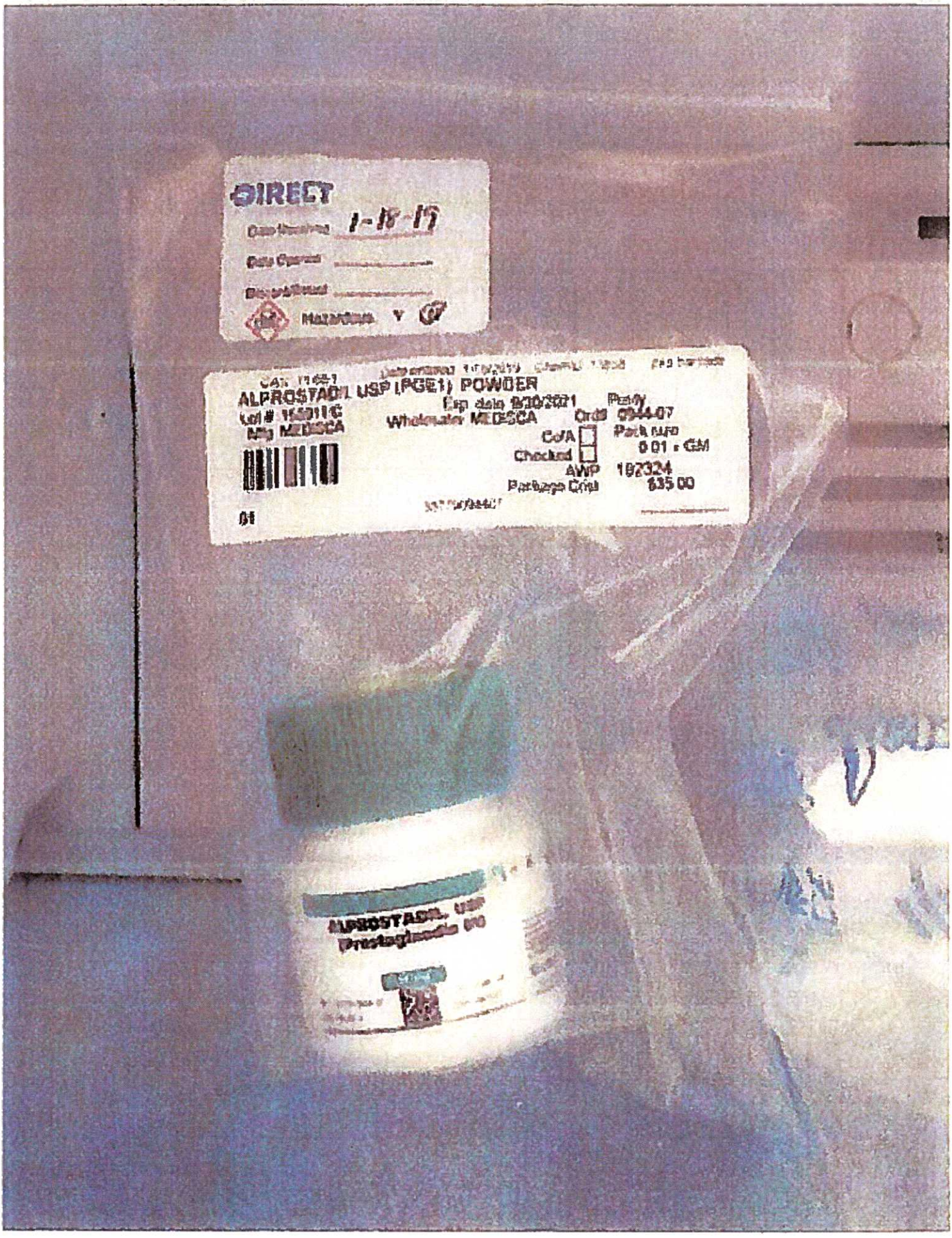



Nandrolone Decanoate
100grams
Distributed By:
B&B Pharmaceuticals, Inc
800-499-3100
CAUTION: For Prescription Compounding Only
Distributed By:
800-499-3100


Nandrolone Decanoate
100grams
Lot# 18H30-BB01-PR0049
Retest: 12/2022
Distributed By:
B&B Pharmaceuticals, Inc.
800-499-3100
Nandrolone Decanoate
25grams
Lot# 18H30-BB01-PR0048
Retest: 12/2022
Distributed By:
B&B Pharmaceuticals, Inc.
800-499-3100


Testosterone Cypion
100grams
Lot# 19A15-BB05-PR00696
Exp: 07/08/2020
Distributed By:
B&B Pharmaceuticals, Inc.
800-499-3100
Testosterone, USP Micr
100grams
Lot# 18K15-BB02-PR00587
Exp: 08/18/2021
Distributed By:
B&B Pharmaceuticals, Inc
800-499-3100


Testosterone Cypionate, US
Distributed By:
Pharmaceuticals, Inc.
800-499-3100
Testosterone, USP Micr
100grams
Lot#18KI5-BB02-PR00587
Distributed By:
B&B Pharmaceuticals, Inc
800-499-3100


DIRECT
1-18-17
ALPROSTADIL USP (PGE1) POWDER
Wholesaler MEDSCA
Checked
AWP 197324
$35.00
ALPROSTADIL USP
Prostaglandin E1

5C

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SCOT SILBER, RPH,** **Certificate of Registration No. 08362,** **Respondent.**	**CASE NO. 19-070-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of June, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

James D. Boyle, Esq.
400 S. 4th Street, Suite 300
Las Vegas NV 89101

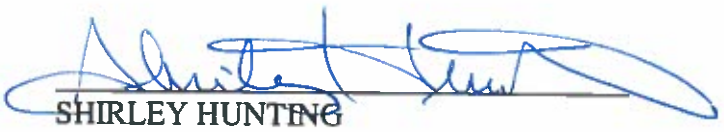
James D. Boyle, Esq.
800 S. Meadows Pkwy., Suite 800
Reno, NV 89521

Scot Silber, R.Ph.
3155 Hazy Hills Ave.
Henderson, NV 89052

Michael Thomas, PT
4260 NEWCASTLE RD
LAS VEGAS, NV, 89103

Krystal Hernandez, PT
9160 Whatley St.
Las Vegas,NV, 89148

Direct Compounding
1850 Whitney Mesa Blvd. #180
Henderson, NV 89014



SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DIRECT COMPOUNDING AND OUTSOURCING, LLC,** **Pharmacy License No. PH04006,** **SCOT SILBER, RPH,** **Certificate of Registration No. 08362,** **MICHAEL THOMAS, PT,** **Certification of Registration No. PT05905,** **KRYSTAL HERNANDEZ, PT** **Certification of Registration No. PT10671,** **Respondents.**	**Case Nos. 19-070-PH-S** **19-070-RPH-S** **19-070-PT-A-S** **19-070-PT-B-S** **STIPULATION AND ORDER FOR RESPONDENT SCOT SILBER, RPH ONLY**

Courtney K. Lee, General Counsel for Petitioner, the Nevada State Board of Pharmacy ("Board"), and Respondent Scot Silber, RPh ("Silber"), Certificate of Registration No. 08362, by and through counsel, James Boyle, Esq. of Holley Driggs, **HEREBY STIPULATE AND AGREE THAT:**

1. The Board has jurisdiction over Respondent Silber and this matter.

2. On or about April 30, 2021, Board Staff served Respondent Silber with the Notice of Intended Action and Accusation ("Accusation") on file in this matter together with the Statement to Respondent and Notice of Hearing. On or about June 2, 2021, Board Staff served Respondent Silber with an Amended Notice of Intended Action and Accusation ("Amended Accusation") together with the Statement to Respondent and Notice of Hearing.

3. On or about May 26, 2021, Respondent Silber filed his Answer and Notice of Defense through retained counsel, James Boyle, Esq. ("Boyle"). On or about June 24, 2021, Respondent Silber, through counsel Boyle, filed his Amended Answer and Notice of Defense.

4. Respondent is aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Amended Accusation, his right to reconsideration, his right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waive his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for certain of the violations alleged in the Amended Accusation, that:

A. Respondent Silber was hired as the managing pharmacist of Direct beginning on or about April 22, 2019. However, on or about April 18, 2019, Respondent Silber supervised and signed off as the pharmacist for Respondent Direct on one 100 batch yield of Oxandrolone 25 mg capsule, and one 30 batch yield of Testosterone Cypionate (6 ml vial) 200 mg/ml injectable. Respondent Silber, as a registered pharmacist, knew or should have known that pharmaceutical technicians, Michael Thomas ("Thomas") and Krystal Hernandez ("Hernandez"), were unlawfully accessing Direct without a pharmacist present. Silber permitted, but did not cause, Thomas and Hernandez to unlawfully access Direct's premises where dangerous drugs and controlled

substances were known to be present, and violated, attempted to violate, assisted or abetted in violation of or conspired to violate NRS 639.220(1), NAC 639.470, NAC 639.520, NAC 639.702, and/or 21 CFR § 1301.71.

8. Those violations are plead with particularity in the Amended Accusation, and are grounds for action pursuant to NRS 639.210(4), (11), (12), (15), and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Silber stipulate to the following penalties and/or conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a registered pharmacist;

B. Respondent shall pay a fine of One-Thousand Five Hundred Dollars ($1,500.00) for the violations; and

C. Respondent shall pay Five-Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

10. Any failure by Respondent Silber to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent Silber, the Board may impose additional discipline upon the non-compliant Respondent consistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 14, 2021. Respondent(s) will appear telephonically or *via* Zoom at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and

deliberate regarding this Stipulation, even if Respondent(s) or counsel are not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Upon approval of this Stipulation by the Board, Respondent shall pay the fines agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

15. Upon approval of this Stipulation by the Board, Respondent shall pay the attorney's fees and costs agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

16. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Amended Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 24 day of June, 2021

SCOT SILBER, RPH,
Certificate of Registration No. 08362

APPROVED AS TO FORM AND CONTENT
this 24th day of June, 2021

JAMES BOYLE, ESQ.
Counsel for Respondent
Scot Silber, RPH

Signed this ___ day of June, 2021

COURTNEY K. LEE, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Scot Silber, RPH, Certificate of Registration No. 08362 in Case No. 19-070-RPH-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of July, 2021.

_____

Helen Park, President
Nevada State Board of Pharmacy

5D

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL THOMAS, PT** **Certificate of Registration No. PT05905,** **Respondent.**	**CASE NO. 19-070-PT-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of June, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

James D. Boyle, Esq.
400 S. 4th Street, Suite 300
Las Vegas NV 89101

James D. Boyle, Esq.
800 S. Meadows Pkwy., Suite 800
Reno, NV 89521

Scot Silber, R.Ph.
3155 Hazy Hills Ave.
Henderson, NV 89052

Michael Thomas, PT
4260 NEWCASTLE RD
LAS VEGAS, NV, 89103

Krystal Hernandez, PT
9160 Whatley St.
Las Vegas,NV, 89148

Direct Compounding
1850 Whitney Mesa Blvd. #180
Henderson, NV 89014

SHIRLEY HUNTING

FILED
JUN 18 2021
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL THOMAS, PT** **Certificate of Registration No. PT05905,** **Respondent.**	**CASE NO. 19-070-PT-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

None

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I admit to having had access to Direct Compounding pharmacy between April 4 2019 and April 22 2019. It was not my intention to run a pharmacy without a licensed pharmacist. It was not my intent to have access to any controlled substances or dangerous drugs.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 14th day of June, 2021.

MICHAEL THOMAS, PT

5E

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRYSTAL HERNANDEZ, PT** **Certificate of Registration No. PT10671,** **Respondent.**	**CASE NO. 19-070-PT-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of June, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KRYSTAL HERNANDEZ, PT** **Certificate of Registration No. PT10671,** **Respondent.**	**CASE NO. 19-070-PT-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

KRYSTAL HERNANDEZ, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

James D. Boyle, Esq.
400 S. 4th Street, Suite 300
Las Vegas NV 89101

James D. Boyle, Esq.
800 S. Meadows Pkwy., Suite 800
Reno, NV 89521

Scot Silber, R.Ph.
3155 Hazy Hills Ave.
Henderson, NV 89052

Michael Thomas, PT
4260 NEWCASTLE RD
LAS VEGAS, NV, 89103

Krystal Hernandez, PT
9160 Whatley St.
Las Vegas, NV, 89148

Direct Compounding
1850 Whitney Mesa Blvd. #180
Henderson, NV 89014

SHIRLEY HUNTING

5F

FILED
MAY 26 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD JENSEN, RPH,** **Certificate of Registration No. 05963,** **JERRY POTMESIL, RPH,** **Certificate of Registration No. 05137, and** **FLYING DIAMOND PHARMACY, LLC,** **License No. PH02114,** **Respondents.**	**CASE NO. 21-036-RPH-A-N** **21-036-RPH-B-N** **21-036-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Richard Jensen, RPh (Jensen), Certificate of Registration No. 05963, and Respondent Jerry Potmesil, RPh (Potmesil), Certificate of Registration No. 05137, were pharmacists registered with the Board, and Respondent Flying Diamond Pharmacy, LLC (Flying Diamond), License No. PH02114, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Flying Diamond is located at 6140 Mae Anne Avenue #1B, Reno Nevada.

3. Jensen was managing pharmacist of Flying Diamond, and Potmesil, Debbie Mandly, PT (Mandly), Certificate of Registration No. PT10527, and Sydney Wilcox (Wilcox), were employees of Flying Diamond at the time of the events alleged herein.

4. On February 15, 2021, an electronic prescription for Trileptal (Oxcarbazpine) 300mg, quantity 105, for patient F.M. was transmitted to Flying Diamond, where pharmaceutical technician Mandly performed data entry in the pharmacy computer system. The computer system designated the prescription as Prescription No. 6211307.

5. During data entry for Prescription No. 6211307, Mandly erroneously filled, labeled and dispensed the prescription for patient K.M. at the Women's Crossroads in Sparks Nevada, where the error was subsequently discovered on or about February 16, 2021.

6. Potmesil is on record as the verifying pharmacist for Prescription No. 6211307. He failed to detect the medication error when he verified data entry as accurate and performed the final product review.

7. On or about March 11, 2021, Flying Diamond pharmacy personnel filled, labeled and dispensed the following prescriptions for patient C.G.:

- Prescription No. 6199803 - Guaifenesin 600mg, quantity 52
- Prescription No. 6203245 - Amantadine 100mg, quantity 52
- Prescription No. 6204749 - Carbamazepine 100mg, quantity 78
- Prescription No. 6206152 - Finasteride 5mg, quantity 26
- Prescription No. 6208635 - Fluoxetine 10mg, quantity 26
- Prescription No. 6206651 - Gabapentin 600mg, quantity 65
- Prescription No. 6206651 - Propranolol 80mg, quantity 26
- Prescription No. 6209912 - Tamsulosin 0.4mg, quantity 26
- Prescription No. 6211650 - Omeprazole 20mg, quantity 26
- Prescription No. 6212179 - Montelukast 10mg, quantity 26

8. On or about March 11, 2021, Flying Diamond pharmacy personnel filled, labeled and dispensed the following prescriptions for patient C.V.-E.:

- Prescription No. 6206313 – Metoprolol 25mg, quantity 60
- Prescription No. 6206806 – Losartan 50mg, quantity 30
- Prescription No. 6209834 - Gabapentin 600 mg, quantity 60

- Prescription No. 6211412 - Lamotrigine 150 mg, quantity 30
- Prescription No. 6212131 - Potassium CL 20 mEq, quantity 30
- Prescription No. 6212132 - Furosemide 80 mg, quantity 30
- Prescription No. 6212292 - Spironolactone 25 mg, quantity 30

9. On March 11, 2021, Wilcox delivered the prescriptions dispensed for C.G. to C.V.-E. at the Women's Crossroads in Spark Nevada, and delivered the prescriptions dispensed for C.V.-E. to C.G. at his residence.

10. On the evening of March 11, 2021, C.V.-E. ingested the following medications dispensed for C.G.:

- Prescription No. 6203245 - Amantadine 100mg, quantity 1
- Prescription No. 6204749 - Carbamazepine 100mg, quantity 1
- Prescription No. 6206651 - Gabapentin 600mg, quantity 1
- Prescription No. 6209912 - Tamsulosin 0.4mg, quantity 1
- Prescription No. 6211650 - Omeprazole 20mg, quantity 1
- Prescription No. 6212179 - Montelukast 10mg, quantity 1

11. On the morning of March 12, 2021, C.V.-E. ingested the following medications dispensed for C.G.:

- Prescription No. 6199803 - Guaifenesin 600mg, quantity 2
- Prescription No. 6203245 - Amantadine 100mg, quantity 1
- Prescription No. 6204749 - Carbamazepine 100mg, quantity 1
- Prescription No. 6206152 - Finasteride 5mg, quantity 1
- Prescription No. 6208635 - Fluoxetine 10mg, quantity 1
- Prescription No. 6206651 - Gabapentin 600mg, quantity 1
- Prescription No. 6206651 - Propranolol 80mg, quantity 1

12. As a direct and proximate result, C.V.-E. experienced a hypertensive crisis and peripheral edema and was admitted to the Renown Regional Medical Center Emergency Room for treatment the morning of March 12, 2021.

13. C.G. discovered the medication delivery error without ingesting any of the prescriptions dispensed for C.V.-E., and notified Flying Diamond.

FIRST CAUSE OF ACTION
Failure to Verify Dispensed Medication/Unprofessional Conduct
(Respondent Potmesil)

14. Unprofessional conduct includes the failure by a licensee to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). It also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). Additionally, NAC 639.252 states in relevant part:

> If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, ***the pharmacist supervising the pharmaceutical technician*** is responsible for the filled prescription, including, but not limited to, verifying:
> (a) The selection and strength of the drug;
> (b) The dosage form; and
> (c) The labeling of the prescription.

NAC 639.252(2) (emphasis added.)

15. Potmesil violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when he verified data entry as accurate and the final product on Prescription No. 6211307 as accurate when it was not, which resulted in the prescription being dispensed to the wrong patient. Potmesil is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

SECOND CAUSE OF ACTION
Managing Pharmacist Responsibilities
(Respondent Jensen)

16. As the managing pharmacist/pharmacist in charge of Flying Diamond at the time of each of the violations alleged herein, Respondent Jensen is responsible for those violations, including all errors and omissions of pharmacy personnel Potmesil, Mandly and Wilcox, pursuant to NRS 639.220(1) and NAC 639.702.

THIRD CAUSE OF ACTION

Pharmacy/Pharmacy Owner Responsibility

(Respondent Flying Diamond)

17. NRS 639.230(5) provides: "Any violation of any of the provisions of this chapter [NRS Chapter 639] by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for the suspension or revocation of the license of the pharmacy by the Board." Additionally, "[t]he owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty at the pharmacy are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission." NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

18. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Flying Diamond is responsible for those violations, including all errors and omissions of pharmacy personnel Jensen, Potmesil, Mandly and Wilcox, pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the registration/license of each Respondent.

Signed this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD JENSEN, RPH,** **Certificate of Registration No. 05963,** **Respondent.**	**CASE NO. 21-036-RPH-A-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD JENSEN, RPH,** **Certificate of Registration No. 05963,** **Respondent.**	**CASE NO. 21-036-RPH-A-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

RICHARD JENSEN, RPH

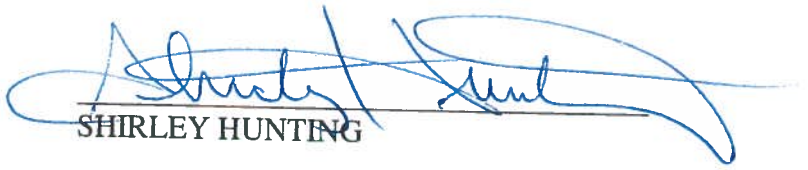
CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Richard Jensen, R.Ph.
P.O. Box 253
Verdi, NV 89439

Jerry Potmesil, R.Ph.
1094 Waverly Drive
Reno, NV 89519

Flying Diamond Pharmacy
6140 Mae Anne Ave. #1B
Reno, NV 89523



SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RICHARD JENSEN, RPH,** **Certificate of Registration No. 05963,** **JERRY POTMESIL, RPH,** **Certificate of Registration No. 05137, and** **FLYING DIAMOND PHARMACY, LLC,** **License No. PH02114,** **Respondents.**	**CASE NOS. 21-036-RPH-A-N** **21-036-RPH-B-N** **21-036-PH-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), Respondent Richard Jensen, RPh (Jensen), Certificate of Registration No. 05963, Respondent Jerry Potmesil, RPh (Potmesil), Certificate of Registration No. 05137, and Respondent Flying Diamond Pharmacy, LLC (Flying Diamond), License No. PH02114, by and through their counsel, Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondents and this matter.

2. On or about May 26, 2021, Board Staff properly served each Respondent with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about July 1, 2021, Respondents jointly filed an Answer and Notice of Defense to the Accusation.

4. Respondents are fully aware of their right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondents are aware of their right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents, or any of them, have failed to comply with the provisions of this Stipulation, Respondents hereby freely and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondents, and each of them, admit that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit,* that:

A. Respondent Potmesil violated NAC 639.252(2) and engaged in unprofessional conduct in violation of NAC 639.945(1)(d) and (i) when he verified data entry as accurate and the final product on Prescription No. 6211307 as accurate when it was not, which resulted in the prescription being dispensed to the wrong patient;

B. As the managing pharmacist/pharmacist in charge of Flying Diamond, Respondent Jensen is responsible pursuant to NRS 639.220(1) and NAC 639.702 for the medication delivery error that directly and proximately resulted in a significant negative outcome to patient C.V.-E. requiring treatment by a medical facility; and

C. As the pharmacy/pharmacy owner at which the violations of law occurred, Flying Diamond is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. Based upon the Accusation and the foregoing admissions, the Board and Respondent Potmesil stipulate to the following penalties. Respondent Jerry Potmesil, RPh, Certificate of Registration No. 05137, shall:

A. Pay a fine of Two Hundred Fifty Dollars ($250.00) for the violations;

B. Pay Two Hundred Fifty Dollars ($250.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter; and

C. Complete two (2) extra hours of continuing education (CE) on error prevention, in addition to the CE hours he must otherwise complete to maintain licensure. Respondent must provide certificates demonstrating that he completed those additional CEs within sixty (60) days of the effective date of this Order.

10. Based upon the Accusation and the foregoing admissions, the Board and Respondent Jensen stipulate to the following penalties. Respondent Richard Jensen, RPh, Certificate of Registration No. 05963, shall:

A. Accept this Order as a public reprimand regarding his duties and responsibilities as a managing pharmacist when delegating tasks to personnel who are not registered pharmacists;

B. Pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations; and

C. Pay Two Hundred Fifty Dollars ($250.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

11. Based upon the Accusation and the foregoing admissions, the Board and Flying Diamond stipulate to the following penalties. Respondent Flying Diamond Pharmacy, LLC, License No. PH02114, shall:

A. Pay a fine of fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations; and

B. Pay Two Hundred Fifty Dollars ($250.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

12. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by that Respondent, the Board may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

13. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 14, 2021. Respondents and their authorized representative(s) will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or their counsel are not present at the meeting.

14. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330.

15. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the

merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order.

17. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and costs agreed to herein by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order.

18. Subject to the approval of this Stipulation by the Board, the Board and Respondents, and each of them, agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents, and each of them, have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of July, 2021

RICHARD JENSEN, RPH
Certificate of Registration No. 05963

Signed this ___ day of July, 2021

Signed this ___ day of July, 2021

JERRY POTMESIL, RPH
Certificate of Registration No. 05137

Signed this ___ day of July, 2021

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

FLYING DIAMOND PHARMACY, LLC
Pharmacy License No. PH02114

APPROVED AS TO FORM AND CONTENT this ___ day of July, 2021

LYN E. BEGGS, ESQ.
Counsel for Respondents

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Richard Jensen, RPh, Certificate of Registration No. 05963, Respondent Jerry Potmesil, RPh, Certificate of Registration No. 05137, and Respondent Flying Diamond Pharmacy, LLC, License No. PH02114, in Case No. 21-036-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of July, 2021.

_____
Helen Park, President
Nevada State Board of Pharmacy

5G

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JERRY POTMESIL, RPH,** **Certificate of Registration No. 05137,** **Respondent.**	**CASE NO. 21-036-RPH-B-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JERRY POTMESIL, RPH,** **Certificate of Registration No. 05137,** **Respondent.**	**CASE NO. 21-036-RPH-B-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

JERRY POTMESIL, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Richard Jensen, R.Ph.
P.O. Box 253
Verdi, NV 89439

Jerry Potmesil, R.Ph.
1094 Waverly Drive
Reno, NV 89519

Flying Diamond Pharmacy
6140 Mae Anne Ave. #1B
Reno, NV 89523

SHIRLEY HUNTING

5H

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FLYING DIAMOND PHARMACY, LLC, License No. PH02114,** **Respondent.**	**CASE NO. 21-036-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Richard Jensen, R.Ph.
P.O. Box 253
Verdi, NV 89439

Jerry Potmesil, R.Ph.
1094 Waverly Drive
Reno, NV 89519

Flying Diamond Pharmacy
6140 Mae Anne Ave. #1B
Reno, NV 89523

SHIRLEY HUNTING

FILED
JUL 7 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 21-036-RPH-A-N**
	)	**21-036-RPH-B-N**
Petitioner,	)	**21-036-PH-N**
	)	
v.	)	
	)	
RICHARD JENSEN, RPH,	)	
Certificate of Registration No. 05963	)	
	)	
JERRY POTMESIL, RPH,	)	
Certificate of Registration No. 05137, and	)	
	)	
FLYING DIAMOND PHARMACY, LLC,	)	
License No. PH02114.	)	
	)	
Respondents.	)	

ANSWER AND NOTICE OF DEFENSE OF RESPONDENTS JENSEN, POTMSEIL AND FLYING DIAMOND PHARMACY

Respondents Richard Jensen, RPH, Jerry Potmesil, RPH and Flying Diamond Pharmacy, LLC ("Flying Diamond"), by and through Wanda Hill, owner of Flying Diamond, hereby files with the Nevada State Board of Pharmacy ("Board"), their Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on May 26, 2021. Mr. Jensen, Mr. Potmesil and Flying Diamond do not have any objection to the Notice of Intended Action and Accusation as being incomplete or failing to clearly state the charges against them.

ANSWER TO ACCUSATION

Mr. Jensen, Mr. Potmesil and Flying Diamond agree that the Board has jurisdiction over each party in this matter and answer the factual allegations as follows:

Factual Allegations: Paragraphs 2-13

Paragraph 2: Mr. Jensen, Mr. Potmesil and Flying Diamond agree with the factual assertion set forth within paragraph 2.

Paragraph 3: Mr. Jensen admits and agrees that he was managing pharmacist at Flying Diamond in February and March 2021.

Paragraph 4: Mr. Jensen and Mr. Potmesil do not have personal knowledge of receipt of the electronic prescription transmitted to Flying Diamond on February 15, 2021, for Trileptal for patient F.M., however a review of records of Flying Diamond verify that this occurred, and that pharmaceutical technician Ms. Mandly entered the prescription, number 6211307, into Flying Diamond's computer system.

Paragraph 5: Mr. Jensen and Mr. Potmesil do not have personal knowledge of Ms. Mandly erroneously filing, labeling and dispensing prescription 6211307, however review of records confirm that Ms. Mandly labeled the prescription for patient K.M. rather than patient F.M. Both F.M. and K.M. resided at Women's Crossroads in Sparks, NV at the time, and both women share the same last name.

Paragraph 6: Mr. Potmesil admits and agrees that he was the verifying pharmacist for prescription number 6211307 and failed to detect the error in labeling the prescription when verifying the data entry and performing final product review.

Paragraph 7: Mr. Jensen, Mr. Potmesil and Flying Diamond have verified that pharmacy personnel did fill, label and dispense the prescriptions listed in paragraph 7 on March 11, 2021, for patient C.V.-E.

Paragraph 8: Mr. Jensen, Mr. Potmesil and Flying Diamond have verified that pharmacy personnel did fill, label and dispense the prescriptions listed in paragraph 8 on March 11, 2021, for patient C.G.

Paragraph 9: Mr. Jensen, Mr. Potmesil have verified that employee Sydney Wilcox did mistakenly delivered the prescriptions filled and dispensed for patient C.V.-E. to patient C.G. and delivered those filled and dispensed for patient C.G. to patient C.V.-E. on March 11, 2021.

Paragraph 10: Mr. Jensen, Mr. Potmesil and Flying Diamond do not have personal knowledge and cannot verify through pharmacy records the factual accuracy of the assertions set forth in paragraph 10.

Paragraph 11: Mr. Jensen, Mr. Potmesil and Flying Diamond do not have personal knowledge and cannot verify through pharmacy records the factual accuracy of the assertions set forth in paragraph 11.

Paragraph 12: Mr. Jensen, Mr. Potmesil and Flying Diamond do not have personal knowledge and cannot verify through pharmacy records the factual accuracy of the assertions set forth in paragraph 12.

Paragraph 13. Mr. Jensen and Mr. Potmesil do not have personal knowledge of the factual assertions set forth in paragraph 13. Ms. Hill, on behalf of Flying Diamond, asserts that patient C.G. contacted Flying Diamond on the morning of March 12, 2021, and that she personally spoke to him and he notified her of the delivery of the prescriptions filled for patient C.V.-E. Ms. Hill immediately picked up the incorrect prescriptions from patient C.G. and Women's Crossroads, was immediately notified of the delivery of the wrong prescriptions for patient C.V.-E. as explained more fully below.

Causes of Action: Paragraphs 14 through 18

First cause of action (naming Respondent Potmesil): Mr. Potmesil acknowledges the accuracy of the Nevada laws set forth in paragraph 14. Mr. Potmesil admits to the allegations set forth in paragraph 15.

Second cause of action (naming Respondent Jensen): Mr. Jensen acknowledges the accuracy of the Nevada laws set forth in paragraph 16 but declines to respond to the allegations set forth therein.

Third cause of action (naming Respondent Flying Diamond): Flying Diamond, by and through Ms. Hill, acknowledges the accuracy of the Nevada laws set forth in paragraph 17. Flying Diamond declines to respond to the allegations set forth in paragraph 18.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Mr. Potmesil readily accepts responsibility in this matter and acknowledges that at the time of the events of February 15, 2021, he failed to detect the errors in data entered by Ms. Mandly when verifying prescription 6211307. While he does believe the fact that the two patients had identical last names and were residing at the same facility was a contributing factor in the mislabeling, he acknowledges that he was responsible as the verifying pharmacist to ensure accuracy in the data. Mr. Jensen, and Ms. Hill on behalf of Flying Diamond, also acknowledge that they are ultimately responsible for the errors and admissions of Mr. Potmesil and Ms. Mandly in this circumstance.

In regard to the misdelivered prescriptions, again, Mr. Jensen and Ms. Hill, on behalf of Flying Diamond acknowledge that they are ultimately responsible for the actions and omission of Ms. Wilcox. When Ms. Hill was contacted at the pharmacy by patient C.G. that he had received the incorrect prescriptions, she immediately picked up the prescriptions and returned them to the

pharmacy. Additionally, pharmacy personnel immediately contacted the on-duty nurse at Northern Nevada Adult Mental Health Services (NNAMHS) regarding the fact that patient C.V.-E. had received the incorrect prescriptions. Women's Crossroads, where patient C.V.-E. resided at the time, is a program of Washoe County which provided transitional housing in addition to on-going medical and behavioral health services for women who have been homeless and are addressing substance abuse issues. NNAHMS oversees the prescriptions received by residents of Crossroads. According to pharmacy personnel, nursing staff at NNAHMS indicated that the delivery had never been verified by NNAHMS staff and they were unaware that patient C.V.-E. had received incorrect prescriptions until notified by Flying Diamond staff.

Flying Diamond is not a pharmacy that is open to the general public for the filling of authorized prescriptions. Flying Diamond primarily fills prescriptions for facilities such as skilled nursing, group homes and programs such as Crossroads. Mr. Jensen, Mr. Potmesil and Ms. Hill on behalf of Flying Diamond have used the two situations set forth in the Accusation to review all internal policies at the pharmacy and to review such policies with all employees of Flying Diamond and to reiterate the need for constant attention to detail at every stage.

Additionally, new policies have been implemented requiring the verifying pharmacist to perform a secondary review of the prescription entry made by the technician prior to a prescription being finalized and prepared for delivery. Flying Diamond has contacted it pharmacy management system, QS-1, to request that it also add the patient's date of birth to the prescription receipt for additional patient verification. Additionally, delivery tickets, used to confirm delivery of prescriptions, have been modified to require the receiving patient and/or caregiver to sign, acknowledging that they have verified that they have received the correct prescriptions for the

correct patient. Finally, Flying Diamond has instituted an "Error/Incident" log for purposes of cataloging and reviewing any such incidents as part of an on-going quality improvement process.

Mr. Jensen has held a registration from the Board since 1972 without any prior action being taken against his registration. Likewise for Mr. Potmesil who has been licensed by the Board since 1997 (and has practiced many years in other state prior to that time). Flying Diamond has been licensed by the Board since 2006 without any adverse action having been taken. Mr. Jensen, Mr. Potmesil and Ms. Hill on behalf of Flying Diamond have taken responsibility for the errors that occurred as set forth in the Accusation. As described above, they have taken this situation very seriously and have utilized it as an opportunity to ensure that the risk of such errors occurring again is minimized as much as possible.

Respectfully submitted this 7th day of July, 2021.



Lyn E. Beggs, Esq.
Attorney for Respondents

5I

FILED 1490
MAY 25 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STEVEN KLOMP, MD,** **Certificate of Registration No. CS01397,** **Respondent.**	**Case No. 19-265-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Steven Klomp, MD, held an expired Nevada controlled substance registration, Certificate of Registration No. CS01397, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew his Certificate of Registration No. CS01397, which expired on October 31, 2018.

3. Respondent wrote seventy prescriptions for controlled substances between November 1, 2018 and December 12, 2019.

4. Respondent renewed his Certificate of Registration No. CS01397 on December 20, 2019.

APPLICABLE LAW

5. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

6. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

7. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

8. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

9. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

10. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

11. The Board may suspend or revoke a registration if the holder has failed to renew a certificate of registration by failing to submit the application for renewal. NRS 639.210(13).

FIRST CAUSE OF ACTION
Failure to Time Renew Controlled Substance Registration

12. By failing to timely renew his Certificate of Registration CS01397, Respondent is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(13) and/or NRS 639.255.

SECOND CAUSE OF ACTION
Violations of Federal Controlled Substances Act

13. By writing seventy prescriptions for controlled substances between November 1, 2018 and December 12, 2019, without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(11) and/or NRS 639.255.

THIRD CAUSE OF ACTION
Violations of State Controlled Substances Act

14. By writing seventy prescriptions for controlled substances between November 1, 2018 and December 12, 2019, without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.255.

FOURTH CAUSE OF ACTION
Commission of Acts that Render Registration Inconsistent with the Public Interest

15. By writing seventy prescriptions for controlled substances between November 1, 2018 and December 12, 2019, without a valid registration, and falsely representing himself as a practitioner entitled to write prescriptions in this state, Respondent committed an act that would render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STEVEN KLOMP, MD,** **Certificate of Registration No. CS01397,** **Respondent.**	**CASE NOS. 19-265-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency

Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STEVEN KLOMP, MD,** **Certificate of Registration No. CS01397,** **Respondent.**	**CASE NO. 19-265-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

STEVEN KLOMP, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Steven Klomp, MD
450 East Main Street
Panaca, NV 89042

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STEVEN KLOMP, DMD,** **Certificate of Registration No. CS01397,** **Respondent.**	**Case No. 19-265-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Steven Klomp, DMD, Certificate of Registration No. CS01397, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about May 25, 2021, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to file an Answer and Notice of Defense to the Accusation prior to entering into this Stipulation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions

of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged in the Accusation, *to wit,* that:

A. Respondent failed to timely renew his Certificate of Registration No. CS01397, which expired on October 31, 2018, in violation of NRS 639.210(13), before renewing his Certificate of Registration No. CS01397 on December 20, 2019; and

B. Respondent wrote seventy prescriptions for controlled substances between November 1, 2018 and December 12, 2019, without a valid registration, and falsely represented himself as a practitioner entitled to write prescriptions in this State, in violation of 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 CFR § 1306.03(a)(1), NRS 453.226(1), NRS 453.321(1)(a), NRS 453.232, NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2813(1).

The Board does not allege that the prescriptions were issued without a legitimate medical purpose in violation of 21 CFR §1306.04 or NRS 453.381, or that Respondent's failure to timely renew his Certificate of Registration No. CS01397 was intentional.

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Steven Klomp, DMD, Certificate of Registration No. CS01397, stipulate to the following penalties:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a prescribing practitioner;

B. Respondent shall pay a fine of Five-Thousand Dollars ($5000.00) for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order;

C. Respondent shall pay Five-Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 14, 2021. Respondent and/or his counsel will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of July, 2021

STEVEN KLOMP, DMD,
Certificate of Registration No. CS01397

Signed this ___ day of July, 2021

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Steven Klomp, DMD, Certificate of Registration No. CS01397, in Case No. 19-265-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of July, 2021.

Helen Park, President
Nevada State Board of Pharmacy

5J

This matter was continued to a future Board Meeting.

5K

FILED 1507
MAY 25 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration No. PD15479,** **Respondent.**	**Case Nos. 20-007-PD-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Jill Oliver, MD ("Oliver"), held a practitioner dispensing registration issued by the Board.

FACTUAL ALLEGATIONS

2. Glimpse Medical ("Glimpse") is a practice located at 5990 S. Rainbow Boulevard #B-1, Las Vegas, Nevada 89118.

3. Respondent Oliver operates Glimpse and has served as the owner/medical director during all relevant timeframes.

4. Diane Racosas ("Racosas") was employed by Glimpse during the relevant timeframes, and performed dispensing technician duties.

5. On January 23, 2020, during an annual inspection of Glimpse, Board inspector found certain violations through inspection and interviews conducted.

6. From 2012 through 2016, Racosas was a licensed dispensing technician for Dr. Oliver. Racosas then took an extended leave. Racosas did not renew her dispensing technician license after 2016.

7. From approximately July 1, 2019 to January 23, 2020, Racosas performed dispensing technician duties without an active dispensing technician license.

8. Dr. Oliver permitted Racosas to be employed in the capacity of dispensing technician at Glimpse without an active dispensing technician license for approximately 115 days.

APPLICABLE LAW

9. No person may act as a dispensing technician unless the person is registered as a dispensing technician. NAC 639.7425(1)(a) and (b).

10. A dispensing practitioner shall not allow any person to act as a dispensing technician without a license/registration. NAC 639.7425(2); NAC 639.744; NAC 639.7445.

11. Performing any duties as the holder of a dispensing registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4), (12), and (13); NRS 639.255.

12. Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NRS 639.255.

13. A business or facility owner is responsible for violations committed by its employees or personnel. NAC 639.945(2).

///

FIRST CAUSE OF ACTION
Dispensing Practitioner Liable

14. By allowing Racosas to act as a dispensing technician without a renewed licensed/registration, Oliver performed her duty as the overseeing dispensing practitioner in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.7425(2), NAC 639.744, NAC 639.7445, NAC 639.945(1)(i) and (j), and is subject to discipline pursuant to NRS 639.210(4), and (12), and/or NRS 639.255.

SECOND CAUSE OF ACTION
Owner Responsibilities

15. As the owner of Glimpse at the time of each of the violations alleged herein, Respondent Oliver is responsible for the violations, including those of her employees, pursuant to NAC 639.945(2), and is subject to discipline pursuant to NRS 639.210(4) and (12) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

DATED this 25th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JILL OLIVER, MD,** **Certificate of Registration No. PD15479,** **Respondent.**	**CASE NOS. 20-007-PD-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency

Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jill Oliver, MD
10170 S. Eastern Ave. #100
Henderson,NV, 89052

SHIRLEY HUNTING

FILED 1514
JUN 28 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. JILL OLIVER, MD, Certificate of Registration No. PD15479, Respondent.	CASE NO. 20-007-PD-S ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

– NONE –

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

My name is Jill Oliver M.D. and I am writing this statement to the State of Nevada Board of Pharmacy. At my yearly pharmacy inspection on January 23rd, 2020 Luis Curras discovered that my dispensing technician license for Dianne Racosas was not valid and up to date. I assured him that we had submitted her application months before when she resumed working for us and told him I would get him the information immediately. After researching things on my end and talking to my office manager we discovered the error we made and took steps to remedy it immediately.

Dianne Racosas was a licensed dispensing technician when she worked for me from 2013 - 2016. She left on maternity leave and was gone for several years. It was during this time that her license expired. She returned to work for me in 2018 but did not perform any dispensing technician duties, only medical assistant duties at another office. When my licensed dispensing technician Samantha Lapalme left my employment in July 2019 Dianne was moved back into the role as dispensing technician.

Somehow, after doing this for so many years, we submitted the "Managing Pharmacist Certification of Pharmaceutical Technician in Training" instead of the " Technician Dispensing in Training Application" for Dianne. Unfortunately, I did not follow up on this mistake so no license was ever generated and Dianne continued to act as a dispensing technician. Upon review of my logs, Dianne Racosas performed technician dispensing duties for 115 days between July 2019 and January 2020. I did not realize that I could go on the Board of Pharmacy website to verify licenses. Of course now it is too late, but had I checked this I would have been able to submit the correct form right away instead of months later.

Please accept my sincere apologies for allowing these errors to occur and know that I take the privilege of being a dispensing practitioner very seriously. I take full responsibility for this and please know that I would never intentionally do anything to jeopardize the privileges you have granted me.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 28th day of June, 2021.

JILL OLIVER, MD

5L

FILED
MAY 26 2021
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KAREN ARCOTTA, MD,** **Certificate of Registration Nos. CS20750 and PD00421,** **Respondent.**	**CASE NO. 21-046-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Karen Arcotta, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS20750, and a Nevada dispensing practitioner registration, Certificate of Registration No. PD00421, both issued by the Board.

FACTUAL ALLEGATIONS

2. On April 21, 2021, Respondent surrendered her DEA Certificate of Registration No. FA2275673 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

3. By executing the DEA Surrender for Cause, Respondent acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

4. On or about April 22, 2021, Board staff served Respondent with notice that her surrender of DEA Certificate of Registration No. FA2275673 for cause operated as an immediate suspension of her Certificate of Registration Nos. CS20750 and PD00421 with the Board pursuant to NRS 639.2107.

5. Respondent wrote two prescriptions for controlled substances on April 22, 2021, after her surrender of DEA Certificate of Registration No. FA2275673.

APPLICABLE LAW

6. It is unlawful to prescribe a controlled substance except as authorized by law. NRS 453.321(1)(a).

7. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

8. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

9. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

10. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

11. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

FIRST CAUSE OF ACTION
Surrender of DEA Registration for Cause

12. By surrendering her DEA Certificate of Registration No. FA2275673 for cause, Respondent has admitted to failing to comply with the Federal requirements pertaining to controlled substances, has committed an act that would render her registration to dispense controlled substances inconsistent with the public interest, is no longer authorized by Federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(11) and NRS 453.241(1).

13. By surrendering her DEA Certificate of Registration No. FA2275673 for cause, the suspension of Respondent's Certificate of Registration Nos. CS20750 and PD00421 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

SECOND CAUSE OF ACTION
Violations of Federal Controlled Substances Act

14. By writing two prescriptions for controlled substances after her surrender of DEA Certificate of Registration No. FA2275673, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(11) and/or NRS 639.255.

THIRD CAUSE OF ACTION

Violations of State Controlled Substances Act

15. By writing two prescriptions for controlled substances after her surrender of DEA Certificate of Registration No. FA2275673, Respondent falsely represented herself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.255.

FOURTH CAUSE OF ACTION

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By writing two prescriptions for controlled substances after her surrender of DEA Certificate of Registration No. FA2275673, and falsely representing herself as a practitioner entitled to write prescriptions in this state, Respondent committed an act that would render her registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KAREN ARCOTTA, MD,** **Certificate of Registration Nos. CS20750 and PD00421,** **Respondent.**	**CASE NOS. 21-046-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, July 14, 2021, at 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive

044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

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

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of May, 2021.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KAREN ARCOTTA, MD,** **Certificate of Registration Nos. CS20750 and PD00421,** **Respondent.**	**CASE NO. 21-046-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2021.

_____

KAREN ARCOTTA, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this, 9th day of June, 2021, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Karen Arcotta, MD
6332 S. Rainbow Blvd., Ste. 110
Las Vegas, NV 89118

SHIRLEY HUNTING

U. S. Department of Justice - Drug Enforcement Administration

DEA USE ONLY

File No.

SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

NAME OF REGISTRANT *(Print)*	ADDRESS OF REGISTRANT
Karen Arcotta	6332 S RAINBOW BLVD STE 110 LAS VEGAS, NV 89118
DEA REGISTRATION NO. FA2275673	
SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL Karen F. Arcotta Karen F. Arcotta	DATE 4/21/21

WITNESSES TO REGISTRANT'S SIGNATURE

NAME AND DATE	TITLE
Jessica Zoeller Jessica Zoeller	Diversion Investigator
NAME AND DATE	TITLE
Cynthia R. Highsmith Cynthia R. Highsmith	Diversion Investigator Group Supervisor

PRIVACY ACT

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
PURPOSE: Permit surrender for cause of DEA Certificate of Registration.
ROUTINE USES: The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
EFFECT: Submission of this information is voluntary. There is no effect on the individual if not provided.

Nevada State Board of Pharmacy

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

April 22, 2021

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO karenarcotta@yahoo.com

Karen Arcotta, MD
6332 S Rainbow Blvd – Suite 110
Las Vegas, NV 89118

Re: Suspension of Certificate of Registration Nos. CS20750 and PD00421 (Case No. 21-046-CS-S)

Dear Dr. Arcotta:

The Nevada State Board of Pharmacy (Board) has been notified by the U.S. Drug Enforcement Administration that you surrendered your DEA Certificate of Registration No. FA2275673 on April 21, 2021 (documentation enclosed).

Please be advised that pursuant to NRS 639.2107 your surrender of your DEA registration operates as an immediate suspension of your Certificate of Registration Nos. CS20750 and PD00421 with the Board. You must immediately CEASE and DESIST from prescribing or dispensing controlled substances. Furthermore, your access to the Nevada Prescription Monitoring Program (PMP) database is terminated effective immediately since you are no longer authorized to access the PMP pursuant to NRS 453.221.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the foregoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,



Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Enclosure

5M

FILED
MAY 26 2020
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFF CHEN, M.D.,** **Certificate of Registration No. CS18013,** **Respondent.**	**Case No. 20-001-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

I.

The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Jeff Chen, M.D. (Chen), held a Nevada Controlled Substance Registration, Certificate No. CS18013, issued by the Board.

FACTUAL ALLEGATIONS

II.

In December 2019, Chen was the medical director of Breathe Bar located on South Center Street in Reno, Nevada.

III.

Amy Burkett (Burkett) owned and operated Breathe Bar. Burkett is not a practitioner licensed by the Nevada State Board of Pharmacy, Nevada State Board of Medical Examiners, Nevada State Board of Osteopathic Medicine, or Nevada State Board of Nursing.

IV.

Breathe Bar employed registered nurses ("RNs").

V.

Breathe Bar 's RN staff provided patient assessments using a proprietary Intravenous (IV)/Intramuscular (IM) Therapy Intake Form. An RN would then communicate his/her assessment of the patient to Chen by telephone or text, in response to which Chen would then approve the medication(s) by telephone or text.

VI.

Chen had no direct contact with, did not examine and did not establish a *bona fide* therapeutic relationship with the patients.

VII.

With Chen's knowledge and authorization and at his direction, Breathe Bar's RN staff provided on-site medical treatment to patients, including the administration of dangerous drugs through intravenous ("IV") therapy and/or injections without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication.

VIII.

Chen directed Breathe Bar's RN staff and Burkett to obtain, access, possess, and store dangerous drugs from Breathe Bar's inventory, and administer dangerous drugs to patients when he was not on site.

IX.

Chen directed Breathe Bar's RN staff to counsel patients regarding their medical treatment, including the administration of dangerous drugs.

X.

Chen permitted opened, undated multi-dose injectables to be used for treatment of Breathe Bar patients.

APPLICABLE LAW

XI.

No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356.

XII.

A practitioner can give a registered nurse (RN) limited authority to possess and administer dangerous drugs without the practitioner on-site by way of NRS 454.213(1)(c), which states in relevant part:

> a drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, *or pursuant to a chart order, for administration to a patient at another location.*

NRS 454.213(1)(a) (*emphasis added*); *see also* NRS 639.100(1).

XIII.

Chart orders must be written (NRS 454.223) and are patient-specific and medication-specific.[1]

XIV.

Multi-dose injectable vials must be dated at the time the seal of the multi-dose container is breached. The contents of the container may be used within 28 days after the breach of the seal occurred. Contents not used within the period set forth may not be used and must be destroyed. NAC 639.67057(2)

---

[1] *See* NRS 639.004 "Chart order" means an order entered on the chart of a patient in a hospital, facility for intermediate care or facility for skilled nursing which is licensed as such by the Division of Public and Behavioral Health of the Department of Health and Human Services or on the chart of a patient under emergency treatment in a hospital by a practitioner or on the written or oral order of a practitioner authorizing the administration of a drug to the patient.

XV.

NAC 639.945 Unprofessional conduct; owner responsible for acts of employees.

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not by way of limitation, unprofessional conduct and conduct contrary to the public interest:

. . . .

(g) Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

(j) Aiding or abetting a person not licensed to practice pharmacy in the State of Nevada.

(k) Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration.

. . . .

(n) Dispensing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship.

. . . .

XVI.

NRS 639.210 Grounds for suspension or revocation of certificate, license, registration or permit or denial of application. The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:

. . . .

4. Is guilty of unprofessional conduct or conduct contrary to the public interest;

. . . .

12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this

> chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;
>
> . . . .

XVII.

The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(d) and NRS 453.241(1).

XVIII.

FIRST CAUSE OF ACTION
Unlawful Access and Possession of Dangerous Drugs (Statutory Violations)

XIX.

By allowing Breathe Bar's RN staff to operate Breathe Bar and to obtain, access, possess administer and/or store dangerous drugs when he was not on site, before he examined the patient, before he wrote a patient-specific order and without his direct supervision, Chen violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213(1), NRS 454.316, NRS 454.221, NRS 454.321, NRS 454.356 and NRS 639.100(1), and is subject to discipline pursuant to NRS 639.210(12).

SECOND CAUSE OF ACTION
Unlawful Access and Possession of Dangerous Drugs (Unprofessional Conduct)

XX.

By allowing Breathe Bar's RN staff to operate Breathe Bar and to obtain, access, possess administer and/or store dangerous drugs when he was not on site, before he examined the patient, before he wrote a patient-specific order and without his direct supervision, Chen performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or

negligent manner, was party to a fraudulent or deceitful practice or transaction, and engaged in, or aided and abetted Breathe Bar's staff to engage in, unprofessional conduct as defined in NAC 639.945(g), (h), (i), (j) and (k), and is subject to discipline pursuant to NRS 639.210(4).

THIRD CAUSE OF ACTION
Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXI.

By authorizing Breathe Bar's RN staff to act under his authority to operate BREATHE BAR, to administer dangerous drugs to patients who had not been examined by a practitioner, with whom Chen did not have a *bona fide* therapeutic relationship and for whom Chen had neither diagnosed or determined that a dangerous drug was medically necessary, Chen engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(o), and is subject to discipline pursuant to NRS 639.210(4).

FOURTH CAUSE OF ACTION
Failure to Follow Procedures Following Breach of the Seal of a Multi-Dose Injectable Container

XXII.

By failing to follow procedures to reflect expiration dates on opened multi-dose injectable vials, Chen violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.67057(2), and is subject to discipline pursuant to NRS 639.210(12).

FIFTH CAUSE OF ACTION
Controlled Substance Registration Inconsistent with the Public Interest

XXIII.

By his actions as set forth herein, Chen has committed acts that render his controlled substance registration inconsistent with the public interest pursuant to NRS 453.231, and is subject to discipline pursuant to NRS 453.236(1)(d) and NRS 453.241(1).

XXIV.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 26th day of May, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file of two copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFF CHEN, M.D.,** **Certificate of Registration No. CS18013,** **Respondent.**	**CASE NO. 20-001-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

III.

The Board has scheduled your hearing on this matter for Wednesday, December 2, 2020, 9:00 a.m. or soon thereafter. The hearing will occur at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada.

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

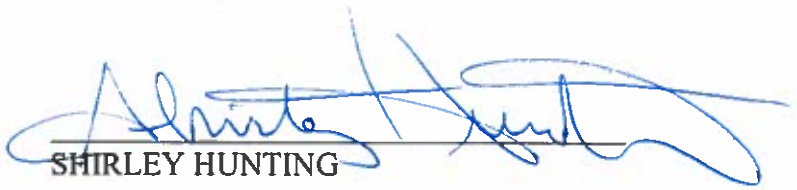
DATED this 26th day of May, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of May, 2020, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Jeff Chen, MD
847 Marsh Avenue
Reno, NV 89509



SHIRLEY HUNTING

FILED
JUL 13 2020
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

-o0o-

NEVADA STATE BOARD OF PHARMACY, Petitioner **V.** **JEFF CHEN, M.D.,** **Certificate of Registration No. CS18013** Respondent	Case No.: 20-001-CS-N **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondent JEFF CHEN, M.D., by and through his counsel of record, EDWARD J. LEMONS, ESQ. and LEMONS, GRUNDY & EISENBERG, and in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds:

The findings alleged misrepresent the roles and actions of Dr. Chen while serving as Medical Director of Breathe Bar for intravenous fluid therapy. On December 19, 2019, Joseph Depczynski, investigator for the Nevada Board of Pharmacy, and Samuel McCord, director of nursing practice for the Nevada Board of Nursing, made an unannounced visit to Breathe Bar stating that there had been a complaint filed regarding questionable practices at the facility which is owned by Amy Burkett. Ms. Burkett is the owner and founder of Breathe Bar, and was present for the site visit. Dr. Chen was not present for the site visit. In

LEMONS, GRUNDY & EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

support of this objection, the statement of Ms. Burkett regarding her recollection of the events that took place that day is attached as **Exhibit A**. It was relayed to her that the complaint was not made by any patient or the result of any patient harm, but likely a competing business in town, however, Mr. Depczynski and Mr. McCord did not provide any further details regarding the identity of the person who filed the complaint. Ms. Burkett provided information regarding Breathe Bar practices with discussion of how they operated the medical treatments at Breathe Bar. At the resolution of the meeting, apparently it was deemed inappropriate that Ms. Burkett had keys to the treatment room and keys to the lock securing the medications utilized for treatment of patients, and the gentlemen confiscated the medications from the locked storage unit and left with the medical inventory. Apparently, however, sometime later, the gentlemen returned to the Breathe Bar and returned the medications stating that they shouldn't have taken the inventory. On information and belief, however, the keys to the storage lock and IV fluid bags were confiscated and Ms. Burkett was instructed that Dr. Chen, as medical director and physician in charge of the medications, would need to contact Mr. Depczynski to set up a meeting where Dr. Chen could obtain the keys in person.

After several attempts, Dr. Chen set up a meeting between him, Mr. David Wuest, the executive secretary of the BOP, Ms. Yenh Long, the deputy secretary of the BOP, and Ms. Burkett on January 3, 2020 to discuss their concerns and repossess the keys to the medications. At that meeting, the representatives for the Board of Pharmacy stated that their concern was related to Ms. Burkett having access to the keys for the locked medications as she was not medically trained or licensed. They also expressed concern regarding the nursing staff having access to the medications, in particular, if Dr. Chen wasn't present on site for the entire treatment period. Dr. Chen reassured Mr. Depczynski and Mr. Wuest that they maintained high levels of security and

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

safety with regards to the medications, and if they felt this was not the case, then they would make any recommended changes they suggested in order to be in compliance. They also detailed to the Board representatives the typical treatment course for patients at Breathe Bar.

Dr. Chen was asked by Amy Burkett to be medical director of Breathe Bar to help assist in developing an intravenous fluid hydration and treatment program for her business. She felt that he was an optimal candidate because of his clinical background in anesthesiology. As a board certified clinician that has treated over 20,000 patients with intravenous fluids for resuscitation of all clinical situations in his 14-year career, and utilized many forms of medications in those treatment protocols, it was felt that Dr. Chen could provide the proper skill set and guidance for her to safely and properly start a program at her health institution. Thus, in May of 2019, Dr. Chen accepted her offer and began developing and establishing protocols to ensure that patients coming through Breathe Bar for treatment would get the same level of care that they could come to expect in a hospital or surgery center setting.

As the medical director, Dr. Chen developed all the necessary intake forms, questionnaires, consent forms including HIPPA compliance, order forms, progress notes, and informational packets for each patient, which were adapted from hospital forms. He also established relationships with accredited distributors of medical supplies and medications/IV fluids and opened an account to procure all the necessary inventory. Dr. Chen established practice protocols for sterility, safety, and compliance that fell in line with those one would see at a hospital or surgery center. And for the first two months of trialing the launch of services at Breathe Bar, Dr. Chen was the sole provider and caretaker for all patients receiving treatment at the facility.

As patient demand grew, Ms. Burkett asked to expand services by recruiting registered nurses to help with the intake and treatment portions of the

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

therapy. All nurses who were employed by Ms. Burkett had been nurses that Dr. Chen directly worked with or were familiar with through his years as an anesthesiologist in the community. They only hired highly competent nurses who had excellent records of service and provided the highest quality care throughout their careers. They were specifically mentored and proctored by Dr. Chen to ensure that the quality measures in place were achieved for each and every patient. Dr. Chen has provided a copy of the nursing guidelines and operating procedures that each new hire was given for reference regarding the expectations he had for them at Breathe Bar, attached hereto as **Exhibit B**.

Based on the guidelines, they maintained strict protocols for how patients were evaluated and treated. In summary, all patients would be evaluated and answer a questionnaire by Dr. Chen and/or a nurse. They would discuss treatment options, benefits, and risks of each treatment option, provide informed consent, and answer any questions from the patient. If nurses provided the initial intake actions, Dr. Chen would go over the findings with each nurse and come up with a treatment plan tailored to the individual needs of every patient. An order form would be filled out and signed by Dr. Chen as the ordering physician, and the nurse would carry out the order and monitor the patient during the infusion treatment. Once the treatment was complete, a final evaluation of the patient was done, and discharge home instructions were provided on what to expect and issues to report. Once the patient was discharged, they would follow-up with the patients the following day to ensure there were no issues or complications.

Reviewing the allegations contained in the Board of Pharmacy's notice letter, the "factual allegations" are objected to as being incomplete, erroneous and the same are denied. The following is to provide further clarification and to correct erroneous statements.

/ / /

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

The nurses and/or Dr. Chen provided patient assessments using the designated intake form which provided a clinical history for each patient. The nurses would communicate with Dr. Chen regarding the assessment for each patient prior to any treatments, and once a clear and defined plan was created, an order would be given on the order sheet which was signed by the physician and carried out by the physician or nursing staff. The false, incomplete, erroneous, and misleading statement is that these orders and communications only occurred via telephone or text, and not in person. Text and telephone messages were used to communicate that patients were ready for their treatment and initial discussions were made via those methods if Dr. Chen was not directly present at the time. Dr. Chen would always come to the facility to sign off on the intake forms, discuss any needs regarding the patient, and sign off on the orders for treatment. This can be verified in all the patient records and charts. It is not unusual that discussions and treatment plans occur over telephone or text messaging. For a physician taking call in the community, there are countless occasions where a nurse will evaluate a patient, call the physician to discuss any issues, and request orders which would be given via telephone or text and signed at a later time. In these instances, physicians are not present on site during these discussions nor when executing an order for the nurse to complete.

Dr. Chen was the primary caregiver for patients when this program was initiated, and thus assessed, examined, treated, and followed-up with every single patient coming through Breathe Bar. When nurses were added to the care team at Breathe Bar, they were expected to follow guidelines for treatment consistent with their nursing requirements. They may have provided initial assessments but contacted Dr. Chen for each patient to discuss and receive orders, and Dr. Chen would be in person to sign orders and verify information gathered by the nurses as evidenced in each patient's medical record. Each

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

patient was counseled by Dr. Chen or the nursing staff, and they knew that at any time, he could be contacted and be present for any issues or questions that arose. See **Exhibit B** for the applicable operating procedures.

Dr. Chen had knowledge and authorized the RNs at Breathe Bar to provide care and treatments to the patients after a thorough evaluation, discussion, and formulation of a safe and adequate plan. Orders were signed and given to provide specific medications and treatments and are readily available for review in the patient records. Of note, the Board of Nursing conducted an investigation of the nurses at Breathe Bar which was initiated by Samuel McCord. **Exhibit C** shows copies of letters which include the Board of Nursing Notice of Investigation, the reply from the nursing staff, and the ultimate decision for the Board of Nursing that they were not practicing independently without supervision and were not practicing outside of their scope, and thus the case was dismissed. Those conclusions support the denial of the allegations and show that the care was provided in accord with state and national standards.

Regarding allegations about the role of Ms. Burkett, she was never directed to handle any of the medication inventory. Dr. Chen was in charge of ordering, stocking, safeguarding, and prescribing the medications. Ms. Burkett had a key to the medication/treatment room, and a key to the lock, but as owner of the facility and as the employer, it was felt that this was appropriate. The nurses had access to the medications to obtain them, but only after receiving an order from the physician. And Dr. Chen kept inventory of all the medications to account for all usage on a weekly basis to ensure there was no issues with expiration or theft. Also, of note, the "dangerous drugs" referenced above specifically dealt with Lactated Ringer's IV solution, ondansetron, ketorolac, Vitamin B, and Vitamin C. From the standpoint of community health concern, it was ensured that they utilized drugs that are commonly used with a high safety

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

profile and there was absolutely no utilization of any Schedule 2 medications. Hydration fluid, anti-nausea medications, non-steroidal anti-inflammatory drugs, and vitamins are widely accepted as being safe, have minimal risks, and patients were screened for risk factors before any treatment. As stated earlier, Dr. Chen has practiced for 14 years and conducted over 20,000 intravenous fluid and medication treatments to patients, and with those particular fluids and medications, has never encountered any issue of fluid overload, QT prolongation (ondansetron), renal failure resulting from afferent vasoconstriction (ketorolac), gastritis (ketorolac), or any other potential side effects from these medications and vitamins. Dr. Chen allowed nurses to perform their duties within their scope of practice, which includes assessing patients, treating patients under physician orders, and administering medications to patients to execute orders provided to them. Please refer to **Exhibit C** for the investigation by the Board of Nursing which found that the nurses acted within their scope of practice while working at Breathe Bar.

The multi-dose medication referenced in the Notice of Intended Action was lidocaine 1% which was used as an anesthetic prior to placement of an intravenous catheter. There were two vials that were uncapped and had not been adequately dated and initialed by the practitioner as is expected for multi-dose vials. This is not a practice that Dr. Chen permitted; however, it was an error that once made aware, was addressed, and taken care of. Dr. Chen reminded both nursing staff and himself of the importance to date and initial when a multi-dose vial is opened, and to discard within 28 days of opening. This was not permitted, and the lidocaine 1% is the only multi-dose medication used at Breathe Bar.

Dr. Chen offers the above explanation and attached documents to correct the misinformation and the vague, incomplete, erroneous, and unclear allegations made against Dr. Chen. Allegations that he engaged in actions

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

constituting "unprofessional conduct or conduct contrary to the public interest" and that he "violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS statutes" are made against him without reasonable basis and in contradiction of the true facts. Those true facts were not verified before these allegations were made against Dr. Chen. At no point during the investigation did anyone from the Board of Pharmacy ask to see how a typical interaction and care for a patient would take place, nor did they witness any normal operating procedures at Breathe Bar. Secondarily, there was no attempt or discussion of any opportunity for improvement or reconciliation of issues that were found. Dr. Chen serves on multiple peer review boards and serves as the chair for that committee at Saint Mary's Regional Medical Center, and knows that it has always been customary for any allegations to be verified either by direct witness or obtaining first-hand testimony of the actions in question. Once this was achieved, it was also customary to specifically speak to person in question directly to get their point of view, and if findings were accurate regarding deficits in the actions, there would be an opportunity for the practitioner to make corrective actions without punitive consequences. Only after repeated episodes would a peer review committee escalate the issue to a level of potential reprimand and punishment. This practice is also consistent with national accrediting bodies like the Joint Commission (JCAHO) and Accreditation Association for Ambulatory Health Care (AAAHC) which oversee operations and compliance of hospitals and surgery centers, respectively. During these direct observation surveys, if deficits are found, the hospitals or surgery centers are given the opportunity to address and rectify any circumstances they deem substandard and would not be punitive without giving an opportunity for correction. Unfortunately, it does not feel that Dr. Chen has been given the same opportunity to correct any perceived deficits to the satisfaction of the Board of Pharmacy. Instead, he is being asked to defend

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

himself to the Board for these "factual allegations" which suggest that he has been derelict of his duty as a medical professional and threaten his standing with the Board.

In closing, Dr. Chen is a native Nevadan and born and raised in Reno. He understandably takes great pride in the city he grew up in and sees his service in the medical community as an opportunity to give back to a community that has given him so much. In his 15-year medical career, he has had a spotless professional record, with no claims against him, being in good standing at all affiliated hospitals and surgery centers, and no issues with any of the Boards for which he serves as a member. He has served in many leadership roles in the community from Medical Director of Surgical Services and member of the Medical Executive Committee at Northern Nevada Medical Center to serving as Medical Director of Surgical Services, Chair of the Professional Peer Review Committee, Chair of Pharmacy and Therapeutics Committee, Vice Chief of Staff, and currently Chief of Staff and Governing Board Member at Saint Mary's Regional Medical Center, and during these times, he has taken pride in serving those positions with integrity, honesty, and responsibility. He currently serves as clinical faculty at the University of Nevada School of Medicine and at Oregon Health and Sciences University in Portland, Oregon in the department of Surgery and Anesthesia, and he always emphasizes to future physicians the importance of doing each patient right and doing no harm, leading by example, and always putting humanity and humility first. He would like the Board to know that he takes his roles and responsibilities as a medical professional seriously and treats every patient as he would a family member. He expects excellence of himself and of his care for each person he encounters. To have these erroneous accusations presented against him is objectionable as stated herein. He will present this case in person to the Board on December 2nd, 2020.

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

2. That, in answer to the Notice of Intended Action and Accusation, he admits, denies and alleges as follows:

JURISDICTION

I.

Respondent admits the allegations contained in paragraph I of the Notice of Intended Action and Accusation.

FACTUAL ALLEGATIONS

II.

Respondent admits the allegations contained in paragraph II of the Notice of Intended Action and Accusation.

III.

Respondent admits the allegations contained in paragraph III of the Notice of Intended Action and Accusation.

IV.

Respondent admits the allegations contained in paragraph IV of the Notice of Intended Action and Accusation.

V.

Respondent denies each and every allegation contained in paragraph V of the Notice of Intended Action and Accusation.

VI.

Respondent denies each and every allegation contained in paragraph VI of the Notice of Intended Action and Accusation.

VII.

Respondent denies each and every allegation contained in paragraph VII of the Notice of Intended Action and Accusation.

VIII.

Respondent denies each and every allegation contained in paragraph VIII of the Notice of Intended Action and Accusation.

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

IX.

Respondent denies each and every allegation contained in paragraph IX of the Notice of Intended Action and Accusation.

X.

Respondent denies each and every allegation contained in paragraph X of the Notice of Intended Action and Accusation.

APPLICABLE LAW

XI.

Respondent denies that the statutes contained in paragraph XI of the Notice of Intended Action and Accusation were violated.

XII.

Respondent denies that the statutes contained in paragraph XII of the Notice of Intended Action and Accusation were violated.

XIII.

Respondent denies that the statute contained in paragraph XIII of the Notice of Intended Action and Accusation was violated.

XIV.

Respondent denies that the statute contained in paragraph XIV of the Notice of Intended Action and Accusation was violated.

XV.

Respondent denies that the statute contained in paragraph XV of the Notice of Intended Action and Accusation was violated.

XVI.

Respondent denies that the statute contained in paragraph XVI of the Notice of Intended Action and Accusation was violated.

XVII.

Respondent denies that the statutes contained in paragraph XVII of the Notice of Intended Action and Accusation were violated.

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

XVIII. (sic)

FIRST CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Statutory Violations)

XIX.

Respondent denies each and every allegation contained in paragraph XIX of the Notice of Intended Action and Accusation.

SECOND CAUSE OF ACTION

Unlawful Access and Possession of Dangerous Drugs (Unprofessional Conduct)

XX.

Respondent denies each and every allegation contained in paragraph XX of the Notice of Intended Action and Accusation.

THIRD CAUSE OF ACTION

Unlawful Administration of Dangerous Drugs – No Bona Fide Therapeutic Relationship and No Authority to Determine Medical Necessity

XXI.

Respondent denies each and every allegation contained in paragraph XXI of the Notice of Intended Action and Accusation.

FOURTH CAUSE OF ACTION

Failure to Follow Procedures Following Breach of the Seal of a Multi-Dose Injectable Container

XXII.

Respondent denies each and every allegation contained in paragraph XXII of the Notice of Intended Action and Accusation.

FIFTH CAUSE OF ACTION

Controlled Substance Registration Inconsistent with the Public Interest

XXIII.

Respondent denies each and every allegation contained in paragraph XXIII of the Notice of Intended Action and Accusation.

LEMONS, GRUNDY & EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

AFFIRMATIVE DEFENSES

Respondent states his Affirmative Defenses as follows:

First Affirmative Defense

Petitioner has failed to state a claim upon which any professional discipline or sanction can be based.

Second Affirmative Defense

The incidents alleged in the Notice of Intended Action and Accusation, and the resulting damage, if any, which this Respondent denies, was caused by the acts of third persons other than Respondent and who are not agents, servants or employees of this Respondent.

Third Affirmative Defense

Respondent did not violate any of the statutes contained in Petitioner's Notice of Intended Action and Accusation.

Fourth Affirmative Defense

Petitioner has failed to provide any information or evidence to prove by a preponderance of the evidence that Respondent violated any of the statutes contained in Petitioner's Notice of Intended Action and Accusation.

Fifth Affirmative Defense

Petitioner has failed to establish via expert affidavit or declaration that Respondent committed malpractice in any manner or violated any additional statutes under NRS 6309 *et al.*.

///

///

///

///

///

///

///

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

WHEREFORE, Respondent prays that the Nevada State Board of Pharmacy determines that Respondent met all applicable standards of care and followed all applicable statutes and did not violate the same.

DATED this 8th day of July, 2020.

LEMONS, GRUNDY & EISENBERG
Attorneys for Respondent
Jeff Chen, M.D.

BY: _____
EDWARD J. LEMONS, ESQ.
Nevada Bar No. 699

LEMONS, GRUNDY
& EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

CERTIFICATE OF SERVICE

I declare that I am an employee of LEMONS, GRUNDY & EISENBERG, and that I am over the age of 18 and not a party to the within action. My business address is 6005 Plumas Street, Third Floor, Reno, NV 89519.

On this date I served a true and correct copy of the ***Answer and Notice of Defense*** by mailing via U.S. Mail to the following:

J. David Wuest, R.Ph, *Executive Secretary*
NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Dated: July 8, 2020

C. Kellman

INDEX OF EXHIBITS

No.	Description	No. Pages
A.	Statement of Amy Burkett	1
B.	Breathe Bar Nursing Guidelines and Operating Procedures	5
C.	Board of Nursing investigation letters to nurses Natisha Zevnick and Natalie Fuller at Breathe Bar; reply letters from Nurse Zevnick and Nurse Fuller; Board of Nursing decision letters to nurses Zevnick and Fuller	8

LEMONS, GRUNDY & EISENBERG
A PROFESSIONAL CORPORATION
6005 PLUMAS STREET
THIRD FLOOR
RENO, NV 89519-6069
(775) 786-6868

breathe bar
MASSAGE · OXYGEN · HYDRATION
777 S. Center Street Suite 201 Reno, NV 89501 775.232.0449 info@renobreathebar.com

To whom it may concern:

In regards to the visit on January 19th by The Nursing Board and Pharmacy Board this is my recount of what happened.

3 Individuals walked into Breathe Bar around 10:30am unannounced. They told me they were doing a courtesy check because of a complaint. Mr. Sam McCord from the Nursing Board handed me a Nursing magazine and told me that in order to be compliant, we had to have a Doctor or Nurse practitioner on site for IVs to be administered. As Dr. Chen and I were told he could be off site but in constant contact with the nurse performing the IV through TigerText a HIPPA certified medical texting app, Facetime or on the phone. I asked both Mr. McCord and Mr. Joe Depczynski which was the exact statute and they were not sure which was lawful or unlawful. They proceeded to tell me what I am doing is unlawful as stated in the article written by Mr McCord. They told me I needed to cease and desist my business immediately. They then asked me to show them the IV treatment room and inspected it thoroughly. When Mr. Depczynski asked me for the key to the refrigerator that held the vitamins, Zofran and Ketorolac I got them from our locked cabinet and let him inspect the meds. After looking at the meds he told me he would need to confiscate said meds and all LR bags I had in the room too. He loaded everything up into a box and took it out of Breathe Bar at approximately noon. He then came back to Breathe Bar around 1:30 with the box of meds and replaced them into the refrigerator and kept the LR and also took the refrigerator key when he left the second time. As my business is still on cease and desist, 4 of the nurses received subpoenas for records for the time they were working with Breathe Bar. After 4 months of waiting, they received full release of all charges by the Board of Nursing. I was forced to remove IV Hydration from Breathe Bar because of this proven "grey area" that is not yet in a NRS for our area.

Dr. Chen did the majority of IVs at Breathe Bar, always with the utmost professionalism. His kind and caring bedside manner always made our customers feel safe and taken care of. His charts were impeccable and thorough. It is disheartening that so many "grey areas" prevented my business from continuing to provide IV Hydration. The one service Dr. Chen and I hoped to provide for our community.

With Regards,

Amy Burkett
Owner, Breathe Bar



Welcome to the Breathe Bar Hydration and Wellness Team!

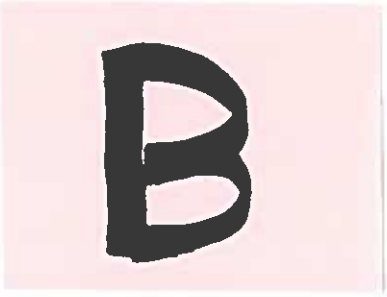
Greetings, I just wanted to introduce myself and explain the goals of our team here at Breathe Bar. Amy Burkett, the owner, has established an amazing establishment for rest, relaxation, rejuvenation, and health at Breathe Bar. She has asked me to serve as Medical Director to help develop and oversee IV hydration therapy and wellness. My background is that I am an anesthesiologist who has worked in town for 10 years, however, like Amy, I am a native and a local. When Amy asked if I would be interested in joining the team, I thought it would be a great opportunity to work with some different people than what I normally deal with, and hopefully it would allow me to see a different way to help people in the community.

My mission statement for our Breathe Bar Hydration and Wellness Team is as follows:

To provide a consistent, exceptional experience that strengthens trust and confidence with our patients, their families, and the community.

I want to make sure every patient experience is of the highest quality and safety, and I am grateful that you have joined the team to help achieve this goal. Even though we are a business in Midtown, I do have some expectations similar to those that we see in the medical arena. My core principles are listed below:

- **Integrity**: We will strive to provide the best and most honest care to each patient. We will practice in a manner which we would expect for each of our own family members. If we have that mindset, we will always provide first class care for all in the community.
- **Professionalism**: We will maintain proper codes of conduct and dress at all times as we are representatives of the medical community as a whole. We also represent Breathe Bar and have a duty to be the best possible stewards for the business and community.
- **Responsibility**: We will practice in a manner that is always above board and work towards achieving a highly reliable medical practice. We will abide by all safety guidelines published my respected medical organizations like the World Health Organization (WHO) and others. We will hold each other accountable to always choose the right.
- **Confidentiality**: We will always respect each individuals privacy and protect their information as we would any patient we care for in the community.
- **Joy**: I want every team member to be happy and enjoy what they are doing. We chose to accept this role because I believe we all wanted to help people, but in a different way than what we are accustomed to. I want this to be a pleasant experience, as our happiness and enthusiasm is palpable and transferable to those that we help!



Patient Intake Forms

- Each patient will receive a patient intake form which will include a demographics and patient history forms, informed consent, HIPAA statement, patient informational sheet, physician order sheet, and progress notes for the procedures.
- For the demographics sheet, important to just ensure that the patient has their name and contact information (i.e. phone number), as we will follow-up with the patients the following day to see how their treatment went.
- For the history intake form, please review all pertinent history, medications, and allergies with the patient. For vital signs, please either document it on the sheet, or else keep a copy so that I can fill in the vitals on my assessment.
- For the informed consent, ensure that each line is initialed and that the patient signs the final sheet. You will also sign the final sheet as well, and I will cosign as well.
- For the HIPAA sheet, inform the patient that we will keep their records private, and they have access to them at any time. Have them sign this sheet as well.
- For the patient orders sheet, we will review the patient history and medical conditions and what the patient requests for treatment. After discussion, I will provide you with an order that you will fulfill for that particular patient. Remember, what the patient requests vs. what we decide and agree upon for treatment may be different. Our order sheet will reflect what we actually decide is best for the patient during their care. I will sign the order sheets and either you or me will fill out the "reviewed by" portion depending on who takes out the medications.
- For the Progress Note, I made sheets that are standardized. Please complete the forms as thoroughly as possible. Please ensure that you sign and date and time the progress notes as these are part of the patient's treatment course and documentation is reflective of what actually happens with the patients.
- For the patient informational sheets, please remove from packet and give to each patient to take home. Notify each patient that we plan on reaching out to them at some point after the treatment to ensure that their care was up their expectations.

IV placement and infusions/IM injections

- Once the intake forms are received and we have reviewed the patient's medical history and developed a treatment plan, I will give orders for what each patient will need. At that point, we begin the treatment phase.
- We shall treat every patient as if we were taking care of them in the hospital, surgery center, or outpatient setting, meaning that we will ensure the same sterility, and precautions as we would in a medical setting.
- Hand washing: either was your hands with soap and water per WHO recommendations or use the sterilizing hand gel *prior to* and *after* each interaction with a patient. After washing your hands, gloves are provided and I request that you use them for each patient during their care.

- Please prep each patient at minimum with alcohol preps before placing an intravenous catheter, or intramuscular injection. Chloroprep sticks will be provided in the IV start kits, and this is superior to the alcohol wipes, so please utilize this as a first option for the IV placement. If multiple attempts are required for a catheter placement, alcohol preps may be used.
- Once an IV is established, ensure that all sharps are placed in the sharps container, and all blood stained items are disposed of in the red hazard bags. Regular trash can be placed in the trash canister.
- Secure IVs as you are comfortable with, but ensure there is adequate fluid flow. Once you start an IV infusion, start with a free flow and monitor for 3-5 minutes to ensure that patient does not have a reaction to the fluids or having difficulty with their IV. Once they have shown the ability to tolerate, you can infuse quicker with the pressure bag if the patient wants a quicker treatment.
- If you have difficulty with IV placement, and it requires more than two attempts, I request that you notify me and I prefer to place the IV at that point in time. Please note that you will still get credit for taking care of the patient and be reimbursed for your care, but I just want to ensure that the patient has a positive experience.
- If medications are ordered and to be injected, please draw up each drug sterily (prep the vial will alcohol before drawing up with a new sterile filter needle and syringe) and deliver it in the selected port slowly (over 15 seconds) once it has been scrubbed with an alcohol prep. Please monitor closely over the next 15 minutes to ensure there is no adverse reactions or symptoms reported by the patient.
- If there an allergic reaction to any medication, please notify me immediately, I will evaluate. If needed, we have epinephrine in the medication refrigerator.
- IM medications should be drawn up sterily and delivered sterily similar to the procedures noted above. Again, please use the filter needle for the glass vials.
- Once the treatment is complete, remove the IV and place all blood stained items in the red hazard bags, and the rest of the trash in the regular trash bin as noted above. Ensure that there is adequate hemostasis and provide bandages or compression bandages as needed.
- Please discuss what to expect with regards to potential side effects such as bruising and/or swelling, bleeding, etc.
- At the end of each of your shift, please check the equipment stock and fill up as needed. If you need something that we are out of, please let me know, and I will order them. Also, if there are items that makes your life easier, let me know as well and I will see if I can get them.

Medications

- For the medications, we will NOT be utilizing any Scheduled drugs (i.e. opioids). From the injectable medications standpoint we will only utilize Zofran (a nausea medication) and Toradol (an anti-inflammatory medication). We may consider adding an antacid medication (Ranitidine) ranitidine in the future. These are given via IV at the dose that I prescribe to you. The major medication for which I may make an adjustment is Toradol based on the patient's age and comorbidities. At our proctoring sessions, I will go over each drug with you, their side effects to look for, and when we would consider not giving the medication.
- For vitamins, we have Vitamin B12, Bcomplex, and C currently, but will see if we want to add any other supplements and vitamins at a later time. These are okay to inject both IM or IV, though we prefer the IM route because it remains in the system a little longer. Again, we will review the risks and benefits of these vitamins at our proctoring session and go over what to expect.
- All medications and vitamins need to be locked up in the refrigerator, and the key will be kept in a safe place with Amy and I have a spare key as well. Please take not of expiration dates for ALL medications before you deliver them.
- I expect everyone to practice the READ pneumonic when administering medications:
    - R- Review every administered drug to make sure it is correct
    - E- Expiration date, ensure it is valid
    - A- Administer according to the route prescribed
    - D- Dosing, ensure that you have the correct amount
- If medications are running low, please notify me directly, I will need to order from our distributor which takes about 3 days.
- IV bags will be brought in weekly and kept in the IV room, I will bring in the amount that is scheduled for the week. Extras will be stored in my office at work, so let me know if extra is needed and I will bring it in but we have a good estimate based on Vagaro scheduling for the week.

Scheduling/Communications

- All scheduling will take place on Vagaro which Amy will set up for you once you are onboarded. Remember, you will not be able to put on the schedule until we complete the two proctored patients so that I can evaluate and provide feedback.
- All schedules will open up for filling once I have determined my availability for the week and I try to do this 2 weeks in advance. It will be a first come first serve basis. We will mostly have weekend slots available for work as I still have clinical duties during the week several weeks throughout the year.
- All communications not patient related can go through normal text, my number is 775-250-2529. All communications regarding PATIENT CARE must go through TigerText, which is our HIPAA compliant app.

- I find that the best flow is to text me when the patient is completing the intake form as I am usually 5 minutes away from Breathe Bar. I will head up, evaluate the patient with you, sign the orders, and you can complete the tasks necessary.
- Once completed, notify the front desk of what procedures you complete for the day and you will receive credit. Amy handles all payroll and payment aspects, so direct any questions regarding that stuff to her.

Essentially, these are the basics to get started. Again, welcome to the Breathe Bar team! If you have any questions, please don't hesitate to ask during our proctoring sessions, or text/call me anytime. I am available to help you out and hopefully you have fun doing something a little different that the typical patient care.

Nevada State Board of
NURSING

January 27, 2020

NOTICE OF COMPLAINT/
INVESTIGATION

Natisha Zevnick
9350 Double R Blvd. 3018
Reno, NV 89521

Re: Complaint submitted by Board staff

Dear Ms. Zevnick:

On December 19, 2019, the Nevada State Board of Nursing Board staff conducted a site survey at Reno Breathe Bar and the findings revealed the following:

> On or about October 15, 2019, through December 15, 2019, while working as a Registered Nurse at Reno Breathe Bar, you allegedly accessed and possessed IV fluids without authorization. You also practiced beyond scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner.
>
> Should these allegations be substantiated, you may have violated the following statutes and/or regulations of the Nevada Nurse Practice Act including but not limited to, NRS 632.347 (1)(g) unprofessional conduct, and/or NAC 632.89 (2) practice beyond scope, (21) obtain, possess, furnish prescription drugs without authorization, and/or (27) customary standards of practice.

Pursuant to NRS 233B.127(3) this letter is to notify you of the allegations and offer you the opportunity to respond if you so choose. The Board will conduct an independent investigation to determine if there has been a violation of the Nurse Practice Act.

Due to the potential for possible action against your license/certificate in Nevada, you need to be aware of the following. You have the right to consult with an attorney before you make any response to the allegations, or at any time during the course of an investigation however, it is not mandatory that you have an attorney represent you in any matters before the Board. Disciplinary action against you may affect a license/certificate issued by the Nevada State Board of Nursing

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-8576 (phone) 775-687-7700 (fa
4220 S. Maryland Pkwy., Suite 300, Las Vegas, NV 89119-7524 (phone) 702-486-5800 (f
www.nevadanursingboard.org • 888-590-6726 • nursingboard@nsbn.state

C

or any other state. In the event that there is formal disciplinary action taken by the Board, you may be charged for all financial costs related to investigation, settlement, and/or formal hearing of the complaint pursuant to NRS 622.400.

If you are a nursing assistant and the complaint is related to abuse, neglect, or misappropriation, the Board will investigate the alleged misconduct on behalf of the Bureau of Health Care Quality and Compliance. The Bureau may place a federal finding on your certificate in addition to any disciplinary action that may be taken by the Board.

Please return your response to the allegation(s) within (2) two weeks of receipt of this letter (as identified by the date upon which you sign the return receipt). Upon completion of the investigation, all information on file regarding the allegations will be reviewed to determine if further steps are appropriate. You will be contacted with the outcome of the investigation.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING

Cindy Peterson, RN
Investigator

Enclosure: Nursing Fact Sheet

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6576 (phone) 775-687-7700 (fax) 775-687-7707
4220 S. Maryland Pkwy, Suite B300, Las Vegas, NV 89119-7533 (phone) 702-486-5800 (fax) 702-486-5803
www.nevadanursingboard.org • 888-590-6726 • nursingboard@nsbn.state.nv.us

To the Nevada State Board of Nursing:

This letter is in response to the letter dated January 24, 2020 addressing the allegation brought against me.

There is an allegation that between the dates of October 15, 2019 and December 15, 2019 I "accessed and possessed IV fluids without authorization and practiced beyond my scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner".

To address the above allegation, I can acknowledge that I was briefly employed by Reno Breathe Bar for the purpose of completing research for a project assigned in a course in my RN to BSN program. My experience at Reno Breathe Bar, though minimal, provided me with insight surrounding available resources in this community that promote overall health and wellness from a holistic and integrative approach compared to those that focus primarily on the prevention and management of disease. Throughout the time frame stated above, I was only present at Reno Breathe Bar on two dates: October 22, 2019 and November 15, 2019. I participated in the care of a total of two patients, only one of which received IV fluids. I was under the direct proctoring supervision of the staff physician, and then, Medical Director, Dr. Jeff Chen during the entirety of each of these patient interactions. At no point in time did I access, possess, nor administer medications and/or IV fluids without the staff physician being physically present, without having received his direct orders after his examination of each patient, nor without acting in accordance with the policies and procedures established by the medical director. All documentation of care supports this.

I am willing and able to answer any further questions and address any other concerns that the Board of Nursing may have, but please understand that I know my scope of practice as a Registered Nurse and that I hold my licensure in the highest regards. I am proud to serve this community as a nurse, and I would not act nor have I acted in a way that compromises my ability to do so and jeopardizes my standing with the Nevada State Board of Nursing. I made a career change to become an RN, and my experience in serving patients in both the Trauma Intensive Care Unit and the Operating Room at Renown has not only reinforced every decision and sacrifice that I made in order to facilitate that change; it has also sparked a desire to continue my education and to grow in this profession. With that being said, please consider that my participation at Reno Breathe Bar was proctored and supervised by the medical director/staff physician, and in no way did I practice outside of my scope of practice as a Registered Nurse.

Sincerely,

Natisha Zevnick, RN 90706

Nevada State Board of NURSING

April 17, 2020

Natisha Zevnick
9350 Double R Blvd. 3018
Reno, NV 89521

Re: Complaint submitted by Board staff

Dear Ms.Zevnick:

This letter is to inform you of the disposition of the Nevada State Board of Nursing regarding the complaint filed against you. After a thorough investigation and review of the evidence, the complaint has been closed. Once an investigation is closed, the contents of the investigation remain confidential. However, if new evidence is discovered, the matter may at any time be opened again and investigated further if circumstances so warrant.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726 ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING

Cindy Peterson, RN
Investigator

Nevada State Board of
NURSING

January 27, 2020

NOTICE OF COMPLAINT/
INVESTIGATION

Natalie Fuller
2250 Watt St.
Reno, NV 89509

Re: Complaint submitted by Board staff

Dear Ms. Fuller:

On December 19, 2019, the Nevada State Board of Nursing Board staff conducted a site survey at Reno Breathe Bar and the findings revealed the following:

> On or about October 15, 2019 through December 15, 2019, while working as a Registered Nurse at Reno Breathe Bar, you allegedly accessed and possessed IV fluids without authorization. You also practiced beyond scope by administering IV fluids to patients who had not been seen and examined by a licensed practitioner.
>
> Should these allegations be substantiated, you may have violated the following statutes and/or regulations of the Nevada Nurse Practice Act including but not limited to, NRS 632.347 (1)(g) unprofessional conduct, and/or NAC 632.89 (2) practice beyond scope, (21) obtain, possess, furnish prescription drugs without authorization, and/or (27) customary standards of practice.

Pursuant to NRS 233B.127(3) this letter is to notify you of the allegations and offer you the opportunity to respond if you so choose. The Board will conduct an independent investigation to determine if there has been a violation of the Nurse Practice Act.

Due to the potential for possible action against your license/certificate in Nevada, you need to be aware of the following. You have the right to consult with an attorney before you make any response to the allegations, or at any time during the course of an investigation however, it is not mandatory that you have an attorney represent you in any matters before the Board. Disciplinary action against you may affect a license/certificate issued by the Nevada State Board of Nursing

or any other state. In the event that there is formal disciplinary action taken by the Board, you may be charged for all financial costs related to investigation, settlement, and/or formal hearing of the complaint pursuant to NRS 622.400.

If you are a nursing assistant and the complaint is related to abuse, neglect, or misappropriation, the Board will investigate the alleged misconduct on behalf of the Bureau of Health Care Quality and Compliance. The Bureau may place a federal finding on your certificate in addition to any disciplinary action that may be taken by the Board.

Please return your response to the allegation(s) within (2) two weeks of receipt of this letter (as identified by the date upon which you sign the return receipt). Upon completion of the investigation, all information on file regarding the allegations will be reviewed to determine if further steps are appropriate. You will be contacted with the outcome of the investigation.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 888-590-6726, ext. 77727.

Sincerely,
NEVADA STATE BOARD OF NURSING

Cindy Peterson, RN
Investigator

Enclosure: Nursing Fact Sheet

Gmail

Natalie Fuller <eagernat@gmail.com>

Response to complaint/allegations by NV State Nursing Board

Natalie Fuller <eagernat@gmail.com> Tue, Feb 4, 8:17 PM
To: info@renobreathebar.com <info@renobreathebar.com>

February 4, 2020

Re: Complaint filed by Board Staff

To the NV State Nursing Board:

This letter is in response to the letter dated January 27th, 2020, and received by me on February 4th,2020.

The allegations stated that between the dates of October 15,2019 through December 15, 2019, while working as an RN at Reno Breathe Bar, that I accessed and administered IV fluids without prior authorization by a licensed practitioner. It states that I practiced beyond my scope.

In response to these allegations, I confirm that I was an employee of Reno Breathe Bar. Per the protocol issued by the Medical Director of Breathe Bar, and reviewed before start of employment, I discussed and reviewed each case with the staff physician. This was done either in person, via the phone, or via HIPPA compliant software Tiger Text. I worked directly under the physician's orders to administer IV fluids and medications. Under no circumstances did I provide care without the prior authorization of the staff physician, and all documentation of patient care reflects this. Neither was I ever in possession of IV fluids without the authorization of the staff physician. After reviewing and discussing each patient case, history, and assessment with the physician, orders were then received and completed.

I can attest that my file as a Registered Nurse is completely clean. I have been a nurse in this state for nearly 38 years, and have never received a complaint from the Board of Nursing. I hold my profession with very high regard, and would not do anything to jeopardize my license or standing with the Board. I have served this community since 1982, from the tiniest of patients in the NICU and Peds ICU, to my present full-time job in Outpatient Radiology.

I am available if there are any more questions, but I assure you that I did not possess IV fluids without authorization, nor did I practice independently while performing my duties at the Breathe Bar.

Should any of this practice be found concerning, I can honestly say that it was completely unintentional. As my first complaint, I sincerely hope that you take into consideration my nursing history and clean record. I am willing to make any necessary changes deemed necessary to stay in compliance with the Board.

Sincerely,

Natalie Jo Fuller

Natalie Jo Fuller
RN License 12814

Nevada State Board of
NURSING

April 17, 2020

Natalie Fuller
2250 Watt St.
Reno, NV 89509

Re: Complaint submitted by Board staff

Dear Ms. Fuller:

This letter is to inform you of the disposition of the Nevada State Board of Nursing regarding the complaint filed against you. After a thorough investigation and review of the evidence, the complaint has been closed. Once an investigation is closed, the contents of the investigation remain confidential. However, if new evidence is discovered, the matter may at any time be opened again and investigated further if circumstances so warrant.

Board staff would issue this statement of caution to you. You must ensure in the future that you practice within your scope as a Registered Nurse in regards to administering IV hydration at remote locations. Board staff recommends you review the article titled "IV Hydration Scope of Practice: What Registered Nurses Need to Know" in the September 2019 issue of the Nevada State Board of Nursing Nursing News. Archived issues of the publication can be obtained on the Board's website: www.nevadanursingboard.org.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726.

Sincerely,
NEVADA STATE BOARD OF NURSING

Cindy Peterson, RN
Investigator

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6576 (phone) 775-687-7700 (fax) 775-687-7707
4220 S. Maryland Pkwy., Suite B300, Las Vegas, NV 89119-7533 (phone) 702-486-5800 (fax) 702-486-5803
www.nevadanursingboard.org • 888-590-6726 • nursingboard@nsbn.state.nv.us

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFF CHEN, MD,** **Certificate of Registration No. CS18013,** **Respondent.**	**Case No. 20-001-CS-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Jeff Chen, MD, Certificate of Registration No. CS18013, by and through counsel**,** Edward J. Lemons, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about May 26, 2020, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about July 13, 2020, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of his right to a hearing on the matters alleged in the Accusation, his right to reconsideration, his right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a

hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that Respondent:

A. Failed at times to put into practice policies and procedures within Breathe Bar to ensure that dangerous drugs were stored, possessed, and administered to patients in compliance with NRS 454.213(1), NRS 454.221 and/or NRS 454.316; and

B. Failed in one instance to record an expiration date on an opened multi-dose injectable vial, in violation of NAC 639.67057(2).

7. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1).

8. Respondent has always practiced as an anesthesiologist, has not had any professional affiliation or engaged in professional practice with Breathe Bar since January 2020, and now confines his practice to anesthesiology.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Jeff Chen, MD, Certificate of Registration No. CS18013, stipulate to the following penalties:

A. Respondent shall accept this Stipulation and Order as a caution regarding his duties and responsibilities as a practitioner when authorizing registered nurses to possess and administer dangerous drugs to patients;

B. Respondent shall pay a fine of One Thousand Five Hundred Dollars ($1500.00) for the alleged violations, payable by *cashier's check* or *certified check* or *money order*

made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order; and

C. Respondent shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly-scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay of suspension, and immediately suspend Certificate of Registration No. CS18013. The Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 14, 2021. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the

merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of July, 2021

JEFF CHEN, MD,
Certificate of Registration No. CS18013

Signed this ___ day of July, 2021

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of July, 2021

EDWARD J. LEMONS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Jeff Chen, MD, Certificate of Registration No. CS18013, in Case No. 20-001-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of July, 2021.

_____
Helen Park, President
Nevada State Board of Pharmacy

6

6A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name **(no abbreviations)**:

First: Aaron Middle: Russell Sprague Last: Borecki

Home Address: Morgan Mill Rd Apt#:

City: Carson City State: NV Zip Code: 89701

Telephone: SS# or ITIN:

Date of Birth: Place of Birth: Fairbanks, AK Sex: ☒ M or ☐ F

E-mail Address:

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number:

I am requesting registration at the following pharmacy:

Pharmacy: Costco Pharmacy Store #: 0127

Address: 700 Old Clear Creek Rd.

City: Carson City State: NV Zip Code: 89705

Signature of Managing Pharmacist: Lic #: 19906 Date: 11/19/2020

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☒ No ☐
2. Are you a high school graduate or the equivalent? Yes ☒ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

	State	Date:	Case #
Board Administrative Action:		/ /	

	State	Date:	Case #:	County	Court
Criminal Action:	NV	7/5/2015	201504356	Carson County	First Judicial District Court

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☒
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Aaron R Borecki

Original Signature, no copies or stamps accepted

11/19/20

Date

Board Use Only Date Processed: **Amount:** 50.00

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

To the Nevada State Board of Pharmacy,

Hello, my name is Aaron Borecki. I am writing this letter regarding the position of Pharmacy Technician that has been offered to me at Costco warehouse #127. Included in this letter are brief summaries, explanations, information, and circumstances that I believe to be important about the misdemeanor that I have been convicted of in the state of Nevada, as well as my first DUI charge. I believe it is also imperative to include my accomplishments over the past few years, as well as the steps that I have undertaken to ensure my past mistakes are not repeated.

On July 6th, 2015, I was arrested and eventually convicted of the charge of possession of a controlled substance, the exact charge being obtaining prescription pills without a prescription. The prescription that I was arrested with was zolpidem. I illegally procured this type of medication because I have always had trouble sleeping, often staying awake for easily more than 24 hours at a time. I had seen a doctor while living in Alaska for my chronic insomnia and was prescribed a few different types of medication for sleep, one of them being Seroquel. Such medications did not improve my sleep in any way and often gave me night terrors and mood swings. I mistakenly decided to take things into my own hands and illegally obtain zolpidem so that I could fall asleep. After moving to Carson City, Nevada in 2012, I continued to use zolpidem in the same manor because it had been working for me. I should have seen a doctor for my condition after relocating, instead of making the foolish decision that I did. After my arrest, I was ordered to complete a substance abuse program with random drug testing, which I completed on March 2nd, 2017. After completion, I immediately went to Carson Medical Group and became a patient of Dr. Bryan Ricks for my chronic insomnia. I was first prescribed Amitriptyline, which gave me heart palpitations. Second, I was prescribed Trazadone, which worked for a while, but its effectiveness over time was lost. Dr. Ricks then decided to put me on zolpidem, which I have now been using effectively for over the past year. I no longer have trouble getting to sleep and getting a good night's rest before going to work and school.

On December 15th, 2018, I graduated with honors from Western Nevada College with an Associates of Arts degree, while also becoming a member of the Phi Theta Kappa Honor Society. It was the single greatest accomplishment of my life. Following my graduation ceremony on May 24th, 2019, three days after my achievement was recognized, I decided to celebrate at a get together with several of my fellow graduates where drinking was involved. Regrettably, I decided to drink a little too much and then chose to drive home shortly after, as I was less than a mile away from my house. I

received my first DUI that night. As my attached records show, I blew .009 over the legal limit on the first BAC test at the station, while on the second test I blew below the legal limit by .03. During my court proceedings, the Honorable Judge John Tatro of Carson City Municipal Court advised me to fight my case because the two test results were not anywhere conclusive in proving what my actual BAC was and that it would not be a good idea to accept that charge of driving under the influence. I respectfully declined, accepting the fact that I should not have been driving and that I had made an extremely poor decision that could have resulted in hurting myself or others on the road. Following my conviction, I completed the required DUI program three months sooner than the allotted time and completed the court mandated period of an interlock device installed on my vehicle. At present, I am still completing school and am currently enrolled in the Certified Nursing Assistant program offered at WNC, as it is one small step toward my future goals. During this time, I have been working at Costco where my employee evaluations have all been rated outstanding. I have been steadily promoted and have received salary increases.

Nothing is more important to me than continuing my schooling and working in the medical field as a career. I have made some poor decisions in my life, decisions that I have learned from and have no intention of repeating. Becoming a part of Costco's pharmacy staff would be an honor for me and the position would help me further my career in the medical field and be another successful step on an upward path. I appreciate you reading my letter and thank you for your time,

Sincerely,

Aaron R. Borecki

Aaron R. Borecki

Aaron R. Borecki

Morgan Mill rd.

Carson City, NV 89701

4 January 2021

To the Nevada State Board of Pharmacy,

My name is Aaron Borecki. I previously sent in paperwork regarding my application for the position of Pharmacy Technician at Costco (#127). In this file is the continuation of the required paperwork that is necessary for the Review Committee to make a final decision. Enclosed are my court documents involving my arrest and conviction in the year 2015, new recommendation letters, including letters previously sent, my school transcript, CPR/AED license, nursing assistance course certificate, Associates of Art diploma, proof of membership in the Honor Society of Phi-Theta Kappa and proof of completion of a specialty court given to me by the Honorable Judge Thomas R. Armstrong. There is also a card with contact information for Jim McCrossin, General Manager at Costco, who has requested that if there are any inquiries about my performance, to not hesitate in reaching out to him for further information.

Within one of my court documents pages there is a line that is whited out. This was the court's action and record formatting when documents are released upon request. Another point that I would like to elaborate on is my original letter. Upon recently receiving my court documents, I realized that I had made an error in my recollection due to the elapsed time since my charge. The crime that I was charged with was possession of a drug not to be introduced to interstate commerce, I had mistakenly thought it was possession of a dangerous drug without a legal prescription. I apologize for this inconvenience and assure the board that I am submitting all the information I can supply, to present a complete picture of who I am.

I would like to mention that I have put consistent effort into the betterment of myself for many years now, graduating with honors from Western Nevada College and continuing my schooling further. I have worked to be the best employee that I can be and my work has been recognized by my superiors. I continue to try to improve upon my goals, ambitions and dreams to the fullest extent. I hope this is taken into consideration when making a final decision in the admittance of myself to the position of Pharmacy Technician.

Sincerely,

Aaron R. Borecki

Aaron R. Borecki

Western Nevada College

05-24-2020

To the Nevada State Board of Pharmacy,

Over the last few years, I have had the opportunity to get to know Aaron Borecki both as a student and as an individual.

As a student, he is hard working, involved, responsible, focused, and engaged. He comes to class prepared, participates in discussions, asks insightful questions, and demonstrates his knowledge and understanding of the material. He is not afraid to ask for clarification of the material and often presents additional perspectives that add insight to the material being discussed. He is also not afraid to come to my office with questions, a demonstration of his desire to not only learn but to understand the material.

As an individual he is kind, cooperative, responsible, detail oriented, considerate of others, driven to succeed, and has a mature, take charge attitude. His care for others is why he is pursuing a career in a field that will allow him to do just that. I think working in the pharmacy industry would be a good fit for his career goals as well as play to his strengths and abilities.

I believe that Aaron has the ability to be successful throughout his educational path. He is focused and responsible. He knows what career he wants and has the maturity and confidence to attain it. If his success in my courses is any indication of his abilities, then he will be a success in his future career as well. Thank you for considering Aaron for a position in the pharmacy industry.

Sincerely,



Dr. Rebecca Bevans

Western Nevada College
2202 W. College Parkway
Carson City, NV 89703
775-445-4449
Rebecca.bevans@wnc.edu

To Whom It May Concern:

It is my pleasure to strongly recommend Aaron Borecki for the position of pharmacy technician with your company.

I am Sonia Zacharias, joint owner and operator of The Wildcat Den Café at Western Nevada College as well as joint owner of Simple Fare Catering in Carson City. I was also an educator in the Carson City School District. I have over 10 years of experience working in the food service/catering business and over 20 years as an educator and have seen many young students/professionals come and go. Aaron is one individual I have worked with who uniquely stands out.

Aaron worked at the WNC Café for a period of 2 years and during that time he displayed a great work ethic, both as a student and as an employee. I was impressed with how he put equal importance on his job and his studies, achieving good grades as well as supervising and training café workers as needed. His attendance was exemplary and he was a good role model for the other students and employees.

It's not just Aaron's work ethic that impressed me, however. His dedication and loyalty, as well as his honesty to us and our business was refreshing. He took a personal interest "looking out" for our best interest when we, the owners, were not there and he was supervising the shift.

I am confident that Aaron would be a great fit for your company. Not only will he bring the kind of skills and experiences you're looking for in an applicant, he will quickly become an asset and help your company thrive in any way he can.

If you need more information or specific examples, please do not hesitate to contact me at . As this recommendation letter likely only provides a snapshot of his skills and achievements, I would be happy to further elaborate on my time working with him.

Sincerely,

Sonia Zacharias

Joint Owner of

Wildcat Den Café and Simple Fare Catering

Western Nevada College
A Member of the Nevada System of Higher Education
www.wnc.edu
Office of the Vice President of Academic Affairs

January 8, 2019

Aaron Borecki
E John St, Apt
Carson City, NV 89701

Dear Aaron Borecki,

It is my great pleasure to inform you that your academic achievements have earned you a place on the Dean's List at Western Nevada College for the Fall 2018 semester. WNC recognizes the academic achievements, integrity, and commitment displayed by an elite group of students on a semester basis.

This honor recognizes that you have maintained 6 credits and a grade point average of 3.5 or above. Achieving this distinction requires drive, determination, and dedication to the extensive requirements of your coursework.

On behalf of the faculty, I congratulate you on this noteworthy achievement and wish you continued success in your studies and endeavors at Western Nevada College.

Sincerely,

Scott Morrison
Vice President of Academic Affairs

Western Nevada College
An Institution of the Nevada System of Higher Education
www.wnc.edu
OFFICE OF THE VICE PRESIDENT OF ACADEMIC & STUDENT AFFAIRS

June 14, 2017

Aaron Borecki
E. John Street
Apt
Carson City, NV 89701

Dear Aaron Borecki,

It is my great pleasure to inform you that your academic achievements have earned you a place on the Dean's List at Western Nevada College for the Spring 2018 semester. WNC recognizes the academic achievements, integrity, and commitment displayed by an elite group of students on a semester basis.

This honor recognizes that you have maintained 12 credits and a grade point average of 3.5 or above. Achieving this distinction requires drive, determination, and dedication to the extensive requirements of your coursework.

On behalf of the faculty, I congratulate you on this noteworthy achievement and wish you continued success in your studies and endeavors at Western Nevada College.

Sincerely,

Scott Morrison
Vice President of Academic and Student Affairs

Western Nevada College
FOUNDATION

July 5, 2018

Mr. Aaron Borecki
E. John Street, Apt.
Carson City, NV 89701

Re: Scholarship Eligibility

Dear Mr. Borecki,

You have received the Eaglemark Savings Bank Scholarship for the 2018/2019 academic year. The following provides information on how to maintain your eligibility for this scholarship.

The Eaglemark Savings Bank Scholarship award amount is $3,000.00; $1,500.00 will be disbursed in the fall, and $1,500.00 will be given in the spring. This award requires that you remain a student in good academic standing with a planned enrollment of twelve or more credits, and maintain a minimum GPA of a 3.0 or above.

Attached is a guideline for writing a thank you letter to your donor. Please, bring or mail your thank you letter to me at Bristlecone 145 within fourteen days of receipt of this letter.

Sincerely,

April Flynt
Development Specialist
WNC Foundation

AF/sc

Carson Medical Group

COPY

Mailing: 1200 Mountain Street • Carson City • Nevada • 89703
CarsonMedicalGroup.com

President
James Breeden, MD

Family Practice
Steven Elliott, MD
Cara-Louise Fox, MD
Timothy Gentner, MD
Sarah Maples, MD
Bryan Ricks, MD
Dustin Riley, MD
Jeffrey Sanders, MD

Obstetrics & Gynecology
Steven Arcangeli, MD
Kira Brooks, MD
Carol Habaradas, MD
Amy Sue Hayes, MD
Shannon Hess, MD
Sandra Koch, MD
Timothy McFarren, MD
Heidi Oberhansli, MD
Katherine Peterson, MD
Ruth Tomita, MD
Wilfredo Torres, MD

Pediatrics
Kathi Amrhein, DO
Patrick Gunn, MD
Brian Hall, MD
Rebecca Papez, MD
Jenny Smokey, MD
Rita Wang, MD

Ear, Nose & Throat
Philip Schlager, MD

07/26/2019

To whom it may concern:

I am writing in regard to my patient Aaron Borecki. Mr. Borecki has been my patient since 2017. He has chronic insomnia which impact his daytime activities of daily living. He has previously been on non-controlled substance medications which are no longer effective. He has been on Zolpidem 10mg at bedtime with good control. It would be medically necessary for him to remain on Zolpidem as non-controlled substance trials have failed. Zolpidem is not a narcotic medication.

Respectfully,

Bryan L. Ricks, M.D.

Western Nevada College

Rachelle Bassen
Biology Instructor
rachelle.bassen@wnc.edu

December 28, 2020

To Whom It May Concern:

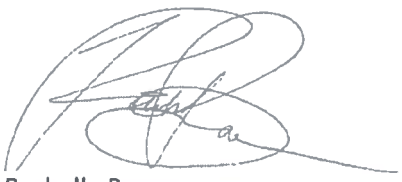
This letter is to recommend Mr. Aaron Borecki for the Pharmacy Technician position. I am qualified to recommend him based on my credentials of teaching as a full-time biology instructor at Western Nevada College. Mr. Borecki successfully completed my Biology 190: Introduction to Cellular and Molecular Biology, BIOL 223: Anatomy & Physiology I, and BIOL 224: Anatomy & Physiology II courses (all lecture and lab-based). He first took BIOL 190 in Fall 2017 and earned a strong grade with a B, then proceeded to A&P I and II in Fall 2019 and Spring 2020, respectively, and ended up earning high A's in those courses. Finding inspiration in his work and narrowing his career interests to pharmacy, he signed up for BIOL 190 in Fall 2020 and earned a high A in that course too.

Mr. Borecki was one of the top students in all my courses and often impressed me with his detailed homework and lab work submissions that demonstrated complex critical thinking skills. It was evident that attention to detail was not just for a grade, but he exceeded expectations to understand the information holistically. Due to his comprehensive effort, he consistently scored some of the top grades on exams. Beyond the rigor that these courses usually consist of, he also successfully navigated two semesters highly disrupted by the COVID-19 pandemic which resulted in having to complete an assortment of at-home and in-person lab experiments (for BIOL 224 and 190). He was highly responsive to the required changes and maintained frequent communication with me.

Regarding his time spent in the in-person labs, he consistently demonstrated his willingness to work with others, asked questions whenever he needed clarification, and aimed for strong work ethic by utilizing his time effectively. He was one of the few people that would also show up for open lab hours to study the anatomy models which helped him to excel on a rather difficult lab exam over the muscles. During our optional cadaver observation/dissection sessions in Fall 2019, Aaron was one of the few students who stepped up to dissect the cadaver.

In summary, I recommend Mr. Aaron Borecki for the pharmacy technician position because of his diligence to complete work with extraordinary quality and ability to communicate effectively with his peers and supervisors to solve problems. His sincere, polite, and respectful attitude towards others means that he will work well with colleagues, supervisors, and customers.

Sincerely,



Rachelle Bassen

December 29, 2020

Aaron Borecki was a Certified Nursing Assistant student of mine during the Fall semester of 2020. Aaron was a wonderful student! He was very punctual in arriving to class which started at 0800 every Monday and Tuesday morning. Aaron was always very polite and respectful to myself and to his fellow students.

Our class was divided into didactic and lab time. He worked in a group of two other students, therefore helping others to achieve their goals in healthcare. He was also willing to go to other students to provide help.

Aaron's grades in the class were excellent, getting A's in all the lecture tests and his final lecture and lab grade. He paid attention when I taught the class by taking notes and concentrating on the Power Points I teach by.

At the end of the semester, we attend what are called Clinical Rotations, in which we go to a local hospital and spend four days learning how to care for patients in an acute hospital setting. It was a little more difficult than usual due to Covid patients that we were not allowed to care for. Aaron stayed busy every day caring for patients and seeing to their needs.

I would recommend Aaron to be able to continue his education in something he enjoys, caring for others.

Yours Truly,

Carole Wiseman RN CWS WCC

Western Nevada College
2202 W. College Parkway
Carson City, NV 89703
(775) 720-4814

Carole.Wiseman@WNC.edu

Carson Medical Group

Summary of Today's Visit

Borecki , Aaron R DOB:
Account No 164187
Gender:Male
Race:White
Ethnicity:Not Hispanic or Latino
Preferred Language:English
07/18/2019 visit with Bryan L Ricks

Allergies

- N.K.D.A.

Medication List

- **Stop TRAZODONE : 50 mg 1 tab(s) orally 1-2 at bedtime,30 day(s) ,60 ,Refills: 5**
- Start Ambien(Zolpidem Tartrate) : 10 MG 1 tablet at bedtime as needed Orally once a day,30 days ,30 ,Refills: 5

Other medications you are on

- Taking TraZODone HCl : 50 MG 1 tablet at bedtime as needed Orally once a day,30 day(s) ,30
- Discontinued TRAZODONE : 50 mg 1 tab(s) orally 1-2 at bedtime,60 ,Refills: 0
- Discontinued Augmentin(Amoxicillin-Pot Clavulanate) : 875-125 MG 1 tablet Orally every 12 hrs,10 day (s) ,20 ,Refills: 0
- Discontinued PrednisONE : 20 MG 2 tablet Orally once a day,5 days ,10 Tablet ,Refills: 0
- Discontinued Ofloxacin : 0.3 % 1 drop into affected eye Ophthalmic Four times a day,5 days ,1 Bottle ,Refills: 1

Notes:
Will start the pt. on Ambien for better sleep control.

Other Medical Conditions (Problem List)

- G47.00 Insomnia
- F51.01 Primary insomnia

Smoking Status

- Former smoker

Your Next Appointment(s)

- Tue, 21 Jan 2020 at 09:15 AM with Bryan L Ricks at Carson Medical Group 1200 Mountain St Carson City, NV 897033821 Phone: 775-882-1324 (Reason: 6 month f/u Ambien)

This document contains confidential information about your health. To maintain your privacy, do not throw this document in the trash. If you do not wish to keep this document for your records, please shred or otherwise securely dispose of your copy. If you are not the intended recipient, please destroy this document and report it to the physician's office named above

DMV
dmvnv.com

OFFICER'S CERTIFICATION OF CAUSE AND NOTICE OF REVOCATION AND/OR SUSPENSION
(NRS Chapters 483 & 484C)

Central Services & Records
555 Wright Way
Carson City, NV 89711
www.dmvnv.com

1. DRIVER'S INFORMATION (PLEASE PRINT)

Name: Borecki (Last) Aaron (First) Russell-Sprague (Middle)

Date Officer completed this form: 5-24-19 (Optional)

Enforcement Agency & City:

Address: Mirror Mill Rd (Street) Carson City (City) NV (State) 89701 (Zip) (Apt.)

Ticket/Case #: 19-344B

DOB: [redacted] ☐ UNDER 18 ☐ UNDER 21

Court:

Sex/Gender M (M/F/X) Height 5'11" Weight 170 Eyes HAZ Hair BRO Class C Endorsements None Restrictions N/A

Vehicle Type: P ☑ Non-Commercial ☐ Commercial ☐ CMV-Hazmat Driver's Lic./ID Card # [redacted] State: NV

Received on above date by (Person's signature):

2. OFFICER'S CERTIFICATION OF CAUSE

I am an Officer employed by the law enforcement agency listed above. On May 24th, 2019, I encountered the above-identified individual (Person) and developed reasonable grounds to believe that the Person had been driving or in actual physical control of a vehicle with a concentration of alcohol above the statutorily prescribed limit in their blood or breath, or a detectable amount of a prohibited or controlled substance in their blood or urine as determined by an evidentiary test. I informed the Person that their license, permit or privilege to drive will be revoked and/or suspended if they fail to submit to evidentiary tests. (NRS 484C.160, 484C.210 and 484C.220)

If Person was UNDER 18 on the date of the evidentiary testing, the Person's parent, guardian, or custodian was notified (per NRS 484C.160).
☐ *The parent, guardian or custodian was NOT notified because:*

3. EVIDENTIARY TEST RESULTS (COPY ATTACHED)

TYPE OF TEST(S) ADMINISTERED:
- ☐ Blood Test (for alcohol or prohibited/controlled substances)
- ☑ Breath Test (for alcohol only)
- ☐ Urine Test (for prohibited/controlled substance)
- ☐ Urine Test (for alcohol - use ONLY for persons afflicted with hemophilia or a heart condition requiring use of an anticoagulant - see NRS 484C 160)
- ☐ *Above-named Person failed to submit to requested evidentiary testing* (officer may apply for a search warrant)

TEST RESULTS — Evidentiary BREATH test results: .089 (Test 1) / .077 (Test 2) / (Test 3)

EVIDENTIARY TEST(S) SHOWED THAT, AT THE TIME OF THE TEST(S), THE PERSON HAD A CONCENTRATION OF ...

PERSONS UNDER 21	☐ *ALCOHOL of 0.02 but less than 0.08 in their blood as determined by a CHEMICAL test*	☐ *ALCOHOL of 0.02 but less than 0.08 in their system as determined by a BREATH test*
PERSONS ANY AGE	☐ *ALCOHOL of 0.08 or more (0.04 or greater if operating a commercial motor vehicle) in their blood as determined by a CHEMICAL test*	☑ *ALCOHOL of 0.08 or more (0.04 or greater if operating a commercial motor vehicle) in their system as determined by a BREATH test*
	☐ *Detectable amount of PROHIBITED or CONTROLLED SUBSTANCE in their blood or urine.*	

Name any pertinent witness or officer J. Hadlock 563B Phone (775) [redacted] 887-2500

Name any pertinent witness or officer [redacted] Phone ( ) [redacted]

4. SERVICE AND NOTICE OF REVOCATION AND/OR SUSPENSION ORDER (Separate from court action)

☐ *I DID NOT SERVE a Notice of Revocation and/or Suspension Order or issue a temporary license on the above-named Person. I request that the Department of Motor Vehicles issue the appropriate Revocation and/or Suspension Order.*

☑ *I SERVED the following Notice of Revocation and/or Suspension Order based on the evidentiary test results or failure to submit as shown above*

THIS IS YOUR OFFICIAL NOTICE OF THE REVOCATION AND/OR SUSPENSION ORDER

You are hereby notified that your driver's license has been revoked and/or suspended* for the following time period:
- *Failure to submit to evidentiary testing: At least 1 year. Additional time may apply for subsequent revocations and/or suspensions.*
- *Evidentiary test result as noted above: 90 days*

**If your license is being revoked based on an evidentiary test showing a concentration of alcohol as noted above or for failure to submit to an evidentiary test, you may apply for a license with an ignition interlock restriction to reinstate your driving privilege. This will include the requirement that you have an ignition interlock device installed, at your own expense, on all vehicles you operate. (See Notes on reverse side of this form)*

If you disagree with the revocation and/or suspension of your driving privileges, YOU MAY REQUEST AN ADMINISTRATIVE HEARING.

☐ *I SEIZED the NEVADA driver's license (if available) and attached it to the Department's copy of this form (pursuant to NRS 484C.220 or 483.462).*

5. TEMPORARY LICENSE/PERMIT *Cannot exceed 7 days* (Officer: See Note 5 on reverse side of this form for effective dates)

This ENTIRE notice must be carried in order to be valid as a Temporary License/Permit. Do not tear off any portion of this form.

ISSUED ON 5-25-19 at 0001 a.m./p.m.

EFFECTIVE DATE 5-25-19 at 0001 a.m./p.m. EXPIRATION DATE 6-1-19

☐ *No temporary license/permit issued because:*

6. LAW ENFORCEMENT OFFICER *I attest that the above information is true and correct.*

Printed Full Name J. Hadlock Badge # 563B Work Phone (775) 887-2500

Officer's Signature [redacted] 563B Date Signed 5-24-19

JUDGMENT AND ORDER OF THE COURT
CARSON CITY JUSTICE AND MUNICIPAL COURT

DEFENDANT: BORECKI, AARON

COURT CASE #: **15 CR 01105 1C** ORIGINATING CASE #: **15-4356** LANGUAGE SPOKEN: **ENGLISH** STATUS: **CLOSED**

PROSECUTING ATTORNEY: **DISTRICT ATTORNEY'S OFFICE** DEFENSE ATTORNEY: **PRO PER**

CHARGE AND SENTENCE INFORMATION

CHARGES: **453.336.2a - POSSESS SCHEDULE I, II, III OR IV CONTROLLED SUBSTANCE, FIRST OR SECOND OFFENSE**

:AMENDED TO: 8.04.125 CS POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE

PLEA: **10/21/2015 - NO CONTEST**
DISPOSITION: **10/21/2015 - GUILTY** JAIL: **SENTENCED TO 180 DAYS IN JAIL SUSPENDED FOR 1 YEAR**

CHARGES: **454.316.1 - POSSESS DANGEROUS DRUG WITHOUT LEGAL PRESCRIPTION, FIRST OR SECOND OFFENSE**

:

PLEA: **NO PLEA**
DISPOSITION: **07/07/2015 - NO CHARGES FILED** JAIL:

CHARGES: **453.566 - USE OR POSSESS DRUG PARAPHERNALIA**

:

PLEA: **NO PLEA**
DISPOSITION: **07/07/2015 - NO CHARGES FILED** JAIL:

CHARGES: **454.510 - POSSESS HYPODERMIC DEVICE**

:

PLEA: **NO PLEA**
DISPOSITION: **07/07/2015 - NO CHARGES FILED** JAIL:

CHARGES: **211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT**

:

PLEA: **02/18/2016 - ADMIT**
DISPOSITION: **02/18/2016 - PROBATION REINSTATED** JAIL: **3 DAYS REVOKED, - 0 DAYS CREDIT, = 3 DAYS TO SERVE, 177 DAYS REMAIN SUSPENDED**

CHARGES: **211A.125 - ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT**

:

PLEA: **02/25/2016 - ADMIT**
DISPOSITION: **02/25/2016 - PROBATION EXTENDED** JAIL: **1 DAYS REVOKED, - 1 DAYS CREDIT, = 0 DAYS TO SERVE, 176 DAYS REMAIN SUSPENDED**

FINES AND FEES

	ORIGINAL AMT	AMT PAID	AMT DISMISSED	AMT DUE
ADDITIONAL FEES	$372.50	$372.50	$0.00	$0.00
	$372.50	$372.50	$0.00	$0.00

TOTAL OWING AS OF THIS DATE $0.00

CONDITIONS INFORMATION

REQUIREMENTS	DUE DATE	CONDITION(S)	COMPLETED

ARREST/BAIL/BOND INFORMATION

ARREST DATE	STATUS DATE	CURRENT STATUS	AMOUNT	TYPE OF BAIL
07/05/2015	10/21/2015	EXONERATED	$50,000.00	BONDABLE
02/18/2016	02/18/2016	ONCE JAIL SENTENCE IS SERVED, RELEASE FROM CUSTODY		
02/24/2016	02/24/2016	JAIL SENTENCE SERVED; RELEASE FROM CUSTODY TODAY.		

NEXT COURT HEARING INFORMATION

NO FUTURE COURT DATE SCHEDULED AT THIS TIME

ADDITIONAL CASE INFORMATION

NO FURTHER INFORMATION

JUDGE'S SIGNATURE:_____ THOMAS ARMSTRONG, 3/2/2017

C%lose
%Open
%Save
%Print

Case Attributes

Case Number15 CR 01105 1C | Filed07/06/201 5 | Case Status | CLOSED | IncmpF 1 | Confidentia | !_

ProsecutoDISTRICT ATTORNEY'S OFFICE > | Judge TATRO, JOHN | Departmen t >

Nbr Type > | Number | Officer Agency | CARSON CITY SHERIFF'S OFFICE > | OfficeHUTT, ERIC r >

JurisdictCARSON CITY ion > | Complainan t >

Defendan t

1 of 1

Full NameBORECKI, AARON > | Def StatusCARSON CITY JAIL | !_Def Status As Of 07/06/20 15

!_ Defendant Disposition

D.O.B. 07/14/1987 S.S.N .

Degree of Offense: FELONY
Degree of Offense: GROSS MISDEMEANOR
Degree of Offense: MISDEMEANOR
Degree of Offense: MISDEMEANOR
Degree of Offense: MISDEMEANOR
Degree of Offense: MISDEMEANOR

Home Address 4540 MORGAN MILL RD
Bad Address SUBARU FORESTER RED

City/ST/Zip CARSON CITY NV 89701 >

At Location 3059 HWY 50 EAST
Attorney >

1 Case Maintenance
2 Docket Entries
3 Parties
4 No Notes
5 Ticklers
6 Costs
7 Events
8 Case Disposition
9 Print Docket
0 Other Records
1 Link Case
2 Citation Information

Def ID Type | Def Number
FBI Number | Gender
Race Cod e | Hair
Height | Weight | Eyes
Other Case Nbr | Court | !_
Charge(s)

1 of 6

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
1	State	D05023M00CC1C	POSSESS DRUG NOT TO BE INTRODUCED INTO INTERSTATE COMMERCE	!_	MISDEMEANOR	GUILTY

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
Amend 07/05/20 15	07/05/2015	5:16PM	NVCCSO5011 562C	15-4356			1 !_

08.04.125 CS, 454.351

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
2	State	D05015G00NV1C	POSSESS DANGEROUS DRUG WITHOUT LEGAL PRESCRIPTION, FIRST OR SECOND OFFENSE	!_	GROSS MISDEMEANOR	NO CHARGES FILED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
07/05/20 15	07/05/2015	5:16PM	NVCCSO5011 562C	15-4356			1 !_

454.316.1, 454.316

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
3	State	D04004M00NV1C	USE OR POSSESS DRUG PARAPHERNALIA	!_	MISDEMEANOR	NO CHARGES FILED

On	(to)	Off Tm	PCN Number	Citation Number	DMV	Bail Amount	Payable
07/05/20 15	07/05/2015	5:16PM	NVCCSO5011 562C	15-4356			1 !_

453.566

Charge	Statute	Action/NOC/Sta	Description	Enhancement	Degree of	Disposition

	Type	tute	Description	Off.			
4	State	D05025M00NV1C	POSSESS HYPODERMIC DEVICE	MISDEMEANOR	NO CHARGES FILED		

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
07/05/2015	07/05/2015	5:16PM	NVCCSO	5011562C	15-4356			1

454.510

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
5	State	W01017W00NV1C	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	PROBATION REINSTATED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
02/11/2016	02/11/2016		NVCCSO	5011562C	15-4356			1

211A.125

Charge	Statute Type	Action/NOC/Statute	Description	Enhancement Description	Degree of Off.	Disposition
6	State	W01017W00NV1C	ARREST OF MISDEMEANOR PROBATIONER FOR VIOLATION OF CONDITION OF PROBATION OR RESIDENTIAL CONFINEMENT		MISDEMEANOR	PROBATION EXTENDED

On	(to)	Off Tm	PCN	Number	Citation Number	DMV	Bail Amount	Payable
02/24/2016	02/24/2016	1:39AM	NVCCSO	5011562C	15-4356			1

211A.125

Total Bail Amount 0.00

Next Event	Appearance Date	Judge	Location

OFFICIAL RECEIPT
CARSON CITY JUSTICE COURT
885 EAST MUSSER ST
STE 2007
CARSON CITY, NV 89701

Date: 12/31/2020 Citation: Case Number: Receipt: 406567

: ID Number:
:

RECEIVED FROM:
AARON

ON BEHALF OF:

PAYMENT FOR:	AMOUNT
RECORDS SEARCH	1.00

PAYMENT TYPE:	REFERENCE NUMBER	AMOUNT PAID
CASH		1.00

RECEIPT TOTAL: 1.00
CHANGE: 0.00

BALANCE DUE 0.00

COMMENTS:

NEXT PAYMENT DATE: NEXT PAYMENT AMOUNT:
COURT RETURN DATE:

NEXT APPEARANCE DATE:

OPERATOR: 1CJMONTOYA
RECEIPT LOCATION: PAYMENT CENTER - CCJC

JUDGE: DEPT:
LOCATION:

This transaction is subject to final audit.

IN THE JUSTICE COURT OF CARSON TOWNSHIP
IN AND FOR CARSON CITY, STATE OF NEVADA

PUBLIC RECORDS REQUEST FORM

Requester's Name: Borecki (Last Name) Aaron (First Name) Russell Sprague (Middle Name)

Requester's Firm/Affiliation (if any): Costco Pharmacy

Requester's Address: Morgan Mill Rd.

Requester's Telephone Number: (775) _____

I would like copies of all public documents for:

Borecki (Last Name) Aaron (First Name) Russell (Middle Name)

Date of Birth: ___ / ___ / ____

Search from: _____ (Month/Year) to _____ (Month/Year)

Requesting:
- [X] Criminal Search
- [ ] Civil Search
- [ ] Both (Criminal & Civil)
- [ ] Traffic

Case Number(s) (if known): _____

I understand there is a cost of $1.00 per calendar year to research the criminal records of the person above named. I agree to pay that amount at the time of making the request (cashier's check or money order payable to Carson City) and enclose a stamped self-addressed envelope.

I also understand if I request a photocopy of any record it shall cost $.50 per page for the record to be photocopied and an additional $3.00 per page if the photocopies are to be certified.

Dated this 31 day of December, 20 20.

Aaron R Borecki
SIGNATURE

PAID

Date: _____

Public Records Request Form/41/PS,W/2.4.16

Western Nevada College

WNC Unofficial Transcripts

Name: Borecki,Aaron Russell Sprague
Student ID:
DOB:

Transfer Credits

Transfer Credit from University of Alaska Fairbanks - Main Location

			Att.	Earned	Points
Course Tran GPA:	0.00	Transfer Tot:	19.00	19.00	0.000

Degrees Awarded

Degree: Associate of Arts
Confer Date: 12/15/2018

Beginning of Undergraduate Record

2015 Spr

Course		Description	Att.	Earned	Grade	Points
HIST	111	Surv of Am Const History	3.00	3.00	B+	9.900
MATH	96	Intermediate Algebra	3.00	3.00	B	9.000
MUS	121	Music Appreciation	3.00	3.00	C+	6.900

			Att.	Earned	GPA Unit	Points
Term GPA	2.87	Term Tot	9.00	9.00	9.000	25.800

2016 Fall

Course		Description	Att.	Earned	Grade	Points
MATH	126	Precalculus Mathematics I	3.00	3.00	C+	6.900

			Att.	Earned	GPA Unit	Points
Term GPA	2.30	Term Tot	3.00	3.00	3.000	6.900

2017 Spr

Course		Description	Att.	Earned	Grade	Points
HIST	101	U.S. History I to 1877	3.00	3.00	A	12.000

			Att.	Earned	GPA Unit	Points
Term GPA	4.00	Term Tot	3.00	3.00	3.000	12.000

2017 Fall

Course		Description	Att.	Earned	Grade	Points
BIOL	190	Intro to Cell & Molec Bio	3.00	0.00	B-	0.000
		Course Repeated - Exclude Units and GPA				
BIOL	190L	Intr Cell & Molec Bio Lab	1.00	1.00	B+	3.300

			Att.	Earned	GPA Unit	Points
Term GPA	3.30	Term Tot	4.00	1.00	1.000	3.300

2018 Spr

Course		Description	Att.	Earned	Grade	Points
CPD	116	Substance Abuse	3.00	3.00	A	12.000
HDFS	202	Intro to Families	3.00	3.00	A	12.000
HIST	105	European Civil to 1648	3.00	3.00	A	12.000
PSY	101	General Psychology	3.00	3.00	A	12.000

			Att.	Earned	GPA Unit	Points
Term GPA	4.00	Term Tot	12.00	12.00	12.000	48.000

Term Honor/Award: Dean's Honors List

2018 Fall

Course		Description	Att.	Earned	Grade	Points
AM	140	American Sign Language I & II	6.00	6.00	A	24.000
GEOG	106	Intro: Cultural Geography	3.00	3.00	A	12.000
NUTR	121	Human Nutrition	3.00	3.00	A	12.000
PSY	233	Child Psychology	3.00	3.00	A	12.000

			Att.	Earned	GPA Unit	Points
Term GPA	4.00	Term Tot	15.00	15.00	15.000	60.000

Term Honor/Award: Dean's Honors List

2019 Spr

Course		Description	Att.	Earned	Grade	Points
AM	141	American Sign Language III&IV	6.00	6.00	B	18.000
PSY	240	Intro to Research Methods	3.00	3.00	A	12.000

			Att.	Earned	GPA Unit	Points
Term GPA	3.33	Term Tot	9.00	9.00	9.000	30.000

2019 Fall

Course		Description	Att.	Earned	Grade	Points
BIOL	223	Human Anatomy & Phys I	4.00	4.00	A-	14.800
CHS	102	Health and Wellness	3.00	3.00	A	12.000

			Att.	Earned	GPA Unit	Points
Term GPA	3.83	Term Tot	7.00	7.00	7.000	26.800

2020 Spr

Course		Description	Att.	Earned	Grade	Points
BIOL	224	Human Anatomy & Phys II	4.00	4.00	A	16.000
PEX	169	Yoga	1.00	1.00	S	0.000

			Att.	Earned	GPA Unit	Points
Term GPA	4.00	Term Tot	5.00	5.00	4.000	16.000

2020 Fall

Course		Description	Att.	Earned	Grade	Points
BIOL	190	Intro to Cell & Molec Bio	4.00	4.00	A	16.000
NURS	130	Nursing Assistant	6.00	6.00	A	24.000

			Att.	Earned	GPA Unit	Points
Term GPA	4.00	Term Tot	10.00	10.00	10.000	40.000

2021 Spr

Course		Description	Att.	Earned	Grade	Points
BIOL	251	General Microbiology	4.00	0.00		0.000

			Att.	Earned	GPA Unit	Points
Term GPA	0.00	Term Tot	4.00	0.00	0.000	0.000

Undergraduate Career Totals

Cum GPA:	3.68	Cum Tot	81.00	74.00	73.000	268.800

End of WNC Unofficial Transcripts

WNC

Deadlines URL

BIOL 251-3001 LEC (27374)	Th 4:00PM - 6:45PM Fallon SAGE 102
BIOL 251-3002 LAB (27375)	Tu 4:00PM - 6:45PM Fallon VRGH 310

other academic...

No Holds.

My Account

You owe 528.00

- Due Now 0.00
- Future Due 528.00

Currency used is US Dollar

Financial Aid

other financial...

Program Advisor

None Assigned

4540 Morgan Mill Rd Carson City, NV 89791	4540 Morgan Mill Rd Carson City, NV 89791
None	aaronkuhn2756@gmail.com

other personal...

You do not have any pending applications at this time

upcoming semester

BASIC LIFE SUPPORT

BLS
Provider

American Heart Association.

Aaron Borecki

has successfully completed the cognitive and skills evaluations in accordance with the curriculum of the American Heart Association Basic Life Support (CPR and AED) Program.

Issue Date
9/15/2020

Training Center Name
Renown Regional Medical Center

Training Center ID
NV03123

Training Center City, State
Reno, NV

Training Center Phone Number
(775) 982-4659

Renew By
09/2022

Instructor Name
Andrea Highfill

Instructor ID
06101893045

eCard Code
205505579786

QR Code

To view or verify authenticity, students and employers should scan this QR code with their mobile device or go to www.heart.org/cpr/mycards.

© 2020 American Heart Association. All rights reserved. 15-3001 R3/20



Driving Under the Influence - DUI Level 1 *an ABC Drive Safe School*

Student Name: Aaron Russell Sprague Borecki

Address:) Morgan Mill Rd.; Carson City, Nevada 89701

Date of Birth

Driver's License #:

State - DL Issued: NV

Citation #:

Judge's Name: Luis

Case #: 19 CR 00765 1C

Court of Jurisdiction #: Carson City Justice/Municipal Court

Court Ordered Completion Date: 09/01/2019

Date of Course Completion: 08/25/2019

Course Final Score: 100

Total Login Time: 9:06:40

This document certifies that the above named person has successfully completed the **8 hour Nevada DMV licensed Level 1 DUI course** DUI000041939. By presenting this signed document to the appropriate agency, court or insurance company swears under penalty of perjury that they are the individual named above who has successfully completed the ABC DUI School on the above date.

08/25/2019

Diane Lund-Shaw
ABC Drive Safe 123 DUI Online
DUI000041939 DUI000045670

Date

634 Ryland Street, Suite 410 • (775) 338-6269 • Email: support@abcdrivesafe.com

1601

JUSTICE AND MUNICIPAL COURT
OF CARSON TOWNSHIP,
CARSON CITY, NEVADA

This certificate is awarded to

AARON BORECKI

IN RECOGNITION OF FAITHFUL COMPLETION OF

SPECIALTY COURT

March 2, 2017

Judge Thomas R. Armstrong

Western Nevada College

Has conferred upon

Aaron Russell Sprague Borecki

the degree of

Associate of Arts

with all the rights and privileges thereunto appertaining.
In witness thereof this diploma duly signed has been
issued and the seal of the College affixed.

Approved by the Board of Regents upon recommendation of the
Faculty on this 15th day of December, 2018.

Chancellor of the
Nevada System of Higher Education

Chairman of the Board of Regents

President

1603

Phi Theta Kappa

This is to Certify That

Aaron Borecki

has complied with all the requirements for,
and has been inducted into

Phi Theta Kappa

Honor Society

Member # 21088060

In witness of which we have caused the great seal of this Society to be hereto affixed and inscribed our signatures.

PHI THETA KAPPA SOCIETY 1918

Geraldine Pope
Chapter Advisor

Alpha Upsilon Beta
Chapter

President and CEO

May 16, 2019
Date

1604

Western Nevada College

This certifies that

Aaron Borecki

Has successfully completed a Nursing Assistant course:

NURS 130 ~ 150 Hours ~

This course is approved by the

Nevada State Board of Nursing Approval No. B501180590

Carole Wiseman

Carole Wiseman, RN
Instructor
December 14, 2020

WESTERN NEVADA COLLEGE

Judith B. Cordia

Judith B. Cordia, EdD, RN
Director of Nursing & Allied Health
December 14, 2020

1605

6B

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Lisa Middle: Marie Last Fuentes

Home Address: [redacted] Heavenly View Court Apt#:

City: Las Vegas State: NV Zip Code: 89117

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: W. Covina California Sex: ☐ M or ☑ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number:

I am requesting registration at the following pharmacy:

Pharmacy: Walgreens Store #: 07842

Address: 3339 S Las Vegas Blvd

City: Las Vegas State: NV Zip Code: 89109

Signature of Managing Pharmacist: Andrew Raymond Lic #: 18420 Date: 2/8/21

(Without the signature of the managing pharmacist, the application will be returned.)

1. **Are you 18 years of age or older?** Yes ☑ No ☐
2. **Are you a high school graduate or the equivalent?** Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☑	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation:**

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
	CA	11/17/1997	FVI 07165	SAN BERNARDINO	Victorville Superior Court
	CA	12/30/1998	FVI 09209	SAN BERNARDINO	Victorville Superior Court

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked YES to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Lisa Fuentes 3/1/21

Original Signature, no copies or stamps accepted — Date

Board Use Only Date Processed: Amount: 50

Check # 1039

Lisa M. Fuentes
[redacted] Heavenly View Ct.
Las Vegas, NV 89117
[redacted]

March 01, 2021

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

To Whom It May Concern:

Per the Board's request, I am enclosing further documentation regarding my criminal history. Due to the advanced age of my two prior cases – one occurred in 1997 (which was later dismissed) and the other in 1998 (which is in the process of dismissal) – the San Bernardino Superior Court does not have the original court files. Instead, the details of my cases can only be obtained through the court's website.[1] (See CA Gov. Code, § 68152 (c)(3)-(5) [providing that trial court clerk may destroy court records depending on type of conviction at issue].) Accordingly, I am enclosing screenshots of the relevant information available on the court's website as to my two prior cases.

I appreciate the Board's time and consideration.

Sincerely,

Lisa Fuentes

Lisa M. Fuentes
[redacted] Heavenly View Ct.
Las Vegas, NV 89117
[redacted]

March 11, 2021

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

To Whom It May Concern:

The following is an account of the events leading up to my arrests in 1997 and 1998, as well as my successful efforts to reform my life. When I was 24 years old, I began associating with people who regularly used methamphetamine, and I began to experiment with the illicit substance as well. These actions led to my arrest in Case Number FVI07165. I pleaded guilty to a misdemeanor offense (CA Health & Saf. Code, § 11378 [possession of a controlled substance for sale]) and I was sentenced to probation and an out-patient drug program. During my probation period, in 1998, I was arrested for possessing a counterfeit $20 bill resulting in the charges in Case Number FVI09209. I pleaded guilty to an additional misdemeanor offense (CA Pen. Code, § 648 [making unauthorized paper money]) and my probation term was extended. Upon my successful completion of probation - including the out-patient drug program - my conviction in Case Number FVI07165 was dismissed. I have also recently filed a petition to dismiss my conviction in Case Number Case Number FVI09209 pursuant to California Penal Code section 1203.4.

I moved to Las Vegas around 2003 and was hired by Walgreens as a service clerk. After about three years, I was promoted to Assistant Manager and currently still hold that position. I have been with the company for about 17 years. During that time, I achieved financial and personal stability, allowing me to better care for my two children. I recognized soon after my offenses that my poor conduct and choices impacted them the most. Disappointing my children was likely the most humiliating experience of my life. Providing stability for them and being a positive role model in their lives is still my biggest motivation in life.

Since my recovery, I have remained in good standing with law and have not relapsed. I was able to put my daughter through college and am very proud of my children's accomplishments. In addition to working full time, I currently care for my elderly mother who has various disabilities, including severe scoliosis. I take responsibility for my past actions but I am also determined to not let them define me. During this horrific pandemic, I reflected on what I could do to help people through my work and how to continue my professional development in order to better support my family. I decided to obtain a tech and training license to accomplish these goals.

I thank the board for its consideration of my application.

Sincerely,

/s/ Lisa Fuentes

Case: FVI07165 - Year occurred - 1997

One charge: HS11378 - Misdemeanor - Dismissed - Case closed.

Case: FVI09209 - Year occurred - 1998

Two charges:

PC476 - Felony - Dismissed - Case closed.

PC648 - Misdemeanor - Sentenced - Successful completion of probation, conviction in the process of dismissal due to the age and no criminal incidents since then.

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

Case Information

FVI09209 | The People of the State of California vs. LISA FUENTES

Case Number FVI09209	Court Victorville Criminal	
File Date 12/30/1998	Case Type Felony	Case Status Closed

Print

Case Information
Party
Charge
Bonds
Disposition Events
Events and Hearings
Financial

Back to top

Party

Plaintiff The People of the State of California	Active Attorneys Lead Attorney Brown, Robert Paul
Defendant FUENTES, LISA MARIE DOB XX/XX/XXXX	Active Attorneys Lead Attorney Public Defender Retained

Charge

FUENTES, LISA MARIE

	Charge	Section	Level	Date
1	PC476-F Making, Possessing, Uttering Fictitious Instrs	476	Felony	12/26/1998
2	PC648 M Make Etc Unauthorized Paper Money	648	Misdemeanor	12/26/1998

Disposition Events

01/27/1999 Plea -

01/27/1999 Plea -

09/09/1999 Plea -

04/05/1999 Disposition -

Nakata, Eric M

1	PC476-Fr Making Possessing Uttering Fictious Instrs	Dismissed

06/04/2001 Disposition -

Nakata, Eric M

2	PC648-Mi Make Etc Unauthorized Paper Money	Convicted

09/09/1999 Sentenced -

2	PC648-Mi Make/Etc Unauthorized Paper Money	Sentenced

Probation

Type: Summary Probation (Court)

Start Date: 09/09/1999

Term: 36 Months

End Date: 03/01/2003

Print

Case Information
Party
Charge
Bonds
Disposition Events
Events and Hearings
Financial

Back to top

Superior Court of California - County of San Bernardino

Register / Sign In

Case Information

FVI07165 | The People of the State of California vs LISA FUENTES

FVI07165	Victorville Criminal	
11/17/1997	Felony	Closed

Print

Case Information
Party
Charge
Disposition Events
Events and Hearings
Financial

Back to top

Party

The People of the State of California

Active Attorneys
Epstein Cary Todd

FUENTES, LISA MARIE
XXXXXXXX

Active Attorneys
Public Defender
Retained

Charge

FUENTES, LISA MARIE

001	HS11378-H Possession Controlled Subst For Sale	11378	Misdemeanor	11/17/1997

Disposition Events

04/22/1998 Plea

04/22/1998 Plea

11/18/1997 Plea

02/04/2003 Amended Disposition

Nakata, Eric M

Modification (Amendment)

001	H511378-M	Possession Controlled Subst For Sale	Dismissed

04/22/1998 Disposition

06/15/1998 Sentenced

Print

Case Information
Party
Charge
Disposition Events
Events and Hearings
Financial

Back to top

6C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Odetta Middle: Kenyetta Last Kilgore

Home Address: S. Boulder HWY Apt#:

City: Henderson State: NEVADA Zip Code: 89015

Telephone: SS# or ITIN:

Date of Birth: Place of Birth: Minnesota Sex: ☐ M or ☒ F

E-mail Address:

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number:

I am requesting registration at the following pharmacy:

Pharmacy: Nevada Career Institute Store #:

Address: 3231 Decatur Blvd Ste 201

City: Las Vegas State: NV Zip Code: 89130

Signature of Managing Pharmacist: Lic #: PT 20827 Date: 12·11·2020

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older?	Yes ☒	No ☐
2. Are you a high school graduate or the equivalent?	Yes ☒	No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation:**

	State	Date:	Case #:	County	Court
Board Administrative Action:	MN	3/ /2013			
Criminal Action:	MN	3/01/2013		Ramsey	

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☒
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Odetta Kilgore — 8-5-2020

Original Signature, no copies or stamps accepted — Date

Board Use Only Date Processed: Amount: 20.00

Check #103845

Odetta Kilgore
. Boulder Highway, Apt.
Henderson, NV. 89015

To Whom It May Concern:

I have no excuse for making the poor decisions, but it's important to try to have these crimes removed so I can continue to lead a productive life.

The four criminal incidents that I will address and none were violent towards others.

Case number 27-VB12-7848, Misdemeanor, Driving after my licenses got revocation gladly to say i have a valid driver. licenses

Case number 27-VB-13-465,Misdemeanor Drivers licenses in possession or fail to display upon request which i'm a licenses holder it has now been 8 years since this charge and it's closed.

Case number 62SU-CR-14-2644 Misdemeanor Theft, I was returning a jacket I had purchased with no receipt. I had the tag when I asked the manager to exchange for another larger jacket. He refused with no receipt so I put the first jacket on the rack and did the exchange without permission. It has been 7 years since this offense.

Case number 27-CR-13-34727, Misdemeanor Theft, I was shopping at Wal-Mart when at the self checkout a pair of $2.88 earrings didn't scan and I was stopped by security when I protested, they call the police. It has been 8 years since this offense.

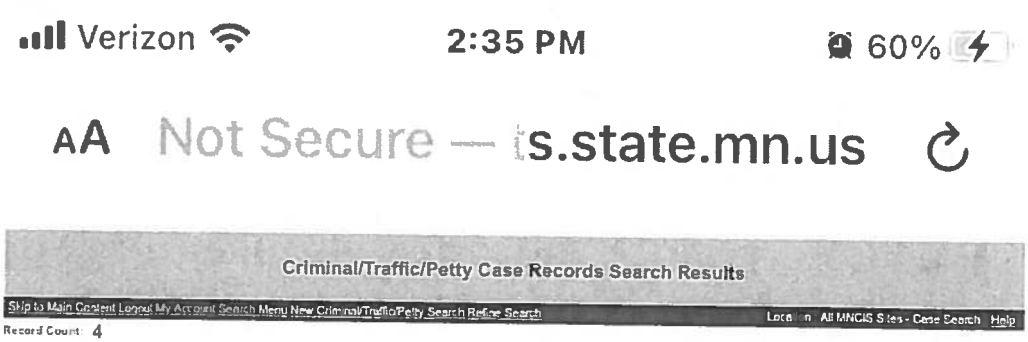
I humbly request that these offenses be set aside because I'm currently living in Las Vegas, Nevada trying to rebuild my life while working for the Clark County School District. I anticipate seeking further employment in the Medical Technology field where I currently hold a diploma for Medical Assistance.

Thank you in advance for your consideration,

Sincerely,

O. Kilgore

Odetta Kilgore



Criminal/Traffic/Petty Case Records Search Results

Skip to Main Content Logout My Account Search Menu New Criminal/Traffic/Petty Search Refine Search Location: All MNCIS Sites - Case Search Help

Record Count: 4

Search By: Defendant **Exact Name:** on **Party Search Mode:** Name **Last Name:** Kilgore **First Name:** Odetta **Middle Name:** Kenyatta **Date of Birth:** 8 All All **Date Filed On or After:** 01/01/2012 **Date Filed On or Before:** 01/01/2021 **Sort By:** Defendant Name

Case Number	Citation Number	Defendant Info	Filed/Location/Judicial Officer	Type/Status	Charge(s)	Disposition/Level of Sentence
27-CR-13-34727	27051212740	KILGORE, ODETTA KENYATTA 03/10/1968	10/21/2013 Hennepin Criminal/Traffic/Petty Southdale	Crim Trial Mandatory Closed	Theft: Take/Use/Transfer Movable Prop-No Consent	Convicted Convicted of a Misdemeanor
27-VB-12-7815	27051212201259	KILGORE, ODETTA KENYATTA 03/10/1968	06/18/2012 Hennepin Criminal/Traffic/Petty Southdale	Crim Trial Non-Mand Closed	Driving after revocation	Convicted Convicted of a Misdemeanor
27-VB-13-408	27111212105139	KILGORE, ODETTA KENYATTA 03/10/1968	01/15/2013 Hennepin Criminal/Traffic/Petty Downtown	Crim Trial Non-Mand Closed	Drivers License - No Drivers License Possession or Fail to Destroy Upon Request	Convicted Convicted of a Misdemeanor
625U-CR-11-2644	6J09205J8130	KILGORE, ODETTA KENYATTA 03/10/1968	07/21/2011 Ramsey Criminal/Traffic/Petty Suburban	Crim Trial Mandatory Closed	Theft: Take/Use/Transfer Movable Prop-No Consent	Convicted Convicted of a Misdemeanor



6D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name **(no abbreviations)**:

First: Barbara Middle: Last Piedra

Home Address: [redacted] Ramrod Ave Apt#: [redacted]

City: Henderson State: NV Zip Code: 89014

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Panorama City, CA Sex: ☐ M or ☑ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number:

I am requesting registration at the following pharmacy:

Pharmacy: DIMA Medical Institute Store #:

Address: 3333 E. Flamingo Rd

City: Las Vegas, State: NV Zip Code: 89121

Signature of Managing Pharmacist: LORINDA LARNER Lic #: PT10792 Date: 12/21/20

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☑ No ☐
2. Are you a high school graduate or the equivalent? Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☑	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
	NV	05/02 / 2020	20CR003006	CLARK	Henderson Municipal Court

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked YES to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Original Signature, no copies or stamps accepted — Date: 11/12/2020

Board Use Only Date Processed: Amount: 50.00

MO# 19147938568

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

Nov 12, 2020

To the State Board of Pharmacy:

I have been considering going back to school for several years now and I am exited to say that I have joined the Pharmacy Tech program at Pima Medical Institute. I have given it a lot of thought and I'm positive that this is the best move I can make towards improving my future. Going to school means so much to me because I want to change my life, I am driven to succeed and make my dreams a reality. My goal is to have a long lasting career, I am the sole provider for my family and need a stable, reliable income during these trying times. I'm looking to improve myself and be a positive role model for my daughter, showing her that anything is possible when you work hard and believe in yourself!

I must admit that I do have an open court case I'm dealing with at the moment. I was arrested for a misdemeanor domestic violence in May 2020. I am currently in the process of taking it to trial, I have not been convicted of anything. I am hoping that the jury will find me not guilty and my case will be closed soon enough.

I recently reviewed the police statements and would like to make it very clear that there are a lot of false allegations made against me. I did not do any of the things I'm being accused of and therefore there is no evidence. As I stated before, I am taking this case to a jury trial where my fate will be decided.

I am more than ready to move past this regretful part of my life. Unfortunately it is a long process and I still have to deal with the possible repercussions until it is completely behind me. All I ask is that you please look past this minor hiccup and open the door to opportunity.

Best Regards,

Barbara Piedra

MUNICIPAL COURT OF THE CITY OF HENDERSON

IN THE COUNTY OF CLARK, STATE OF NEVADA

CITY OF HENDERSON, NEVADA,

Plaintiff,

vs.

BARBARA PIEDRA,

Defendant.

2020 MAY -7 10:34

CRIMINAL COMPLAINT

CASE NO.
20CR003006 (PCN 1)

Nicholas G. Vaskov, Esq., City Attorney

The defendant has committed the crime of:
BATTERY CONSTITUTING DOMESTIC VIOLENCE (Misdemeanor - Henderson Municipal Code 8.02.055) within the City of Henderson, in the County of Clark, State of Nevada, in the manner following, that the said defendant, on or about May 2, 2020:

did willfully and unlawfully use force or violence against or upon the person's spouse, former spouse, any other person to whom the person is related by blood or marriage, any person with whom the person has had or is having a dating relationship, any person with whom the person has a child in common, the minor child of any of those persons or his minor child or any other person who has been appointed the custodian or legal guardian for the person's minor child, to-wit: Did strike Stephen Foster III one or more times and/or did push him, all of which occurred in the area of 1309 Cedar Berry Court.

All of which is contrary to the form, force and effect of statutes in such cases made and provided and against the peace and dignity of the City of Henderson, State of Nevada. Said Complainant makes this declaration on information and belief subject to the penalty of perjury.

Ashley [illegible] for

Marc M. Schifalacqua, Esq.
Sr. Assistant City Attorney

Dated: May 4, 2020
CAO File #: 030045
PCN#: NVHP5142919C

2

Henderson Municipal Court Sentencing Order ☑ Original ☐ Amended

1625

Name: Reda Bahra

Fines:

Case #	Original	Suspend	Imposed	Case #	Original	Suspend	Imposed
21CR13116							
				Subtotal from today's fines			+
				Prior outstanding fine balance			+
				☐ Good Faith Payment ☐ Credit for Time Served			-
				$50 Payment Setup Fee			+
				Total: $			

☐ Complete and Submit Traffic Safety School Completion Certificate by: ____/____/____ ☐ Level 1 ☐ Level 2 (Repeat Offenders)
☐ Pay your fine in full by: ____/____/____ ☐Pay $_____ by ___/___/___ and balance by ___/___/___
☐Time Payments:Monthly Minimum payment of $_____. **$50.00 payment set-up fee will be added to total due.**
Beginning ____/____/____, until fine is paid in full ☐Add to Existing Payments ☐Payments Reset

Mail Payments to: Henderson Municipal Court, PO Box 95050 - MS621, Henderson, NV 89009
On-line payments: www.cityofhenderson.com/municipal_court/

☐ Present valid NV Driver's License to ☐ dismiss /☐ reduce to $_____ /☐ to suspend fine/ ☐ amend to "No DL in Possession"
☐ Present valid Registration to ☐ dismiss / ☐ reduce to $_____ / ☐ to suspend fine
☐ Present valid Insurance to ☐ dismiss / ☐ reduce to $_____
☐ Present proof of _____ to ☐ dismiss / ☐reduce to $_____ / ☐ to suspend fine

Present proof of the above to Customer Service Windows by: ____/____/____

☐ No Further Arrests/Citations ☐Same / Similar ☐Any Criminal for a period of _____ months / duration
☐ Complete the following by ___/___/___☐ Coroner's Visitation Program ☐ NV Vehicle Safety Program
☐ Victim's Impact Panel (You must provide the completion certificate on or before your return court date/completion date)
☐ D.R.I.V.E on ___/___/___ ☐ Other_____
If completed by due date: ☐ Suspend $_____ ☐ Dismiss ☐ Amend to_____

☐ **WORK PROGRAM:** Complete _____ hours at a **minimum rate of 5 hours per week** – *One time setup fee applies*
You must appear in person to the Special Programs and Services (SPS), located at 243 Water Street, Lower Level, Henderson, NV immediately following court or upon the first business day following your release from custody. Failing to appear at the Special Programs and Services, failing to comply with the court's order, or receipt of a non-compliant report may result in a Bench Warrant issued for your arrest. You must report to Special Programs and Services as directed throughout the term of Supervision. You must provide correct contact information to Special Programs and Services and report any changes of that information immediately.

☑ Your next court date will be for:
☐ Arraignment ☐Trial ☐Sentencing ☑Status Check ☐Show Cause ☐Attorney Status ☐Good Faith Payment $_____
on: 12/16/21 @ 10:00 AM / PM in Dept. 1 / 2 / 3
☑ Appearance Required ☐ Appearance Not Required if compliant with ALL orders
Failure to Appear for a required court appearance will result in a BENCH WARRANT being issued for your arrest.

*Comments:_____

FAILURE TO COMPLY WITH ANY ORDER OF THE COURT MAY RESULT IN ADDITIONAL FEES AND/OR A BENCH WARRANT FOR YOUR ARREST

Date: 11/3/21 Clerk HM
Dept. 1 / 2 / 3
Original=Court / Yellow=SPS / Pink=Def Rev. 4/30/18

Henderson Municipal Court

PUBLIC DEFENDER'S OFFICE

NOTICE OF APPOINTMENT – Dept. 2

DEFENDANT'S NAME Pietra, Barbara **PHONE #** [redacted]

CASE #(S) 20C230306

CHARGE(S) DV

PRESENTLY IN CUSTODY ☐ YES ☒ NO

NEXT COURT DATE 8/25/2020 **TIME:** 10:00 **AM / PM DEPT.** 2

The Henderson Municipal Court Public Defender's Office will only represent your charge(s) in the Henderson Municipal Court. The office of the Department 2 Public Defender, Ann Purser, is located in the Justice Facility at 243 Water Street, 3rd Floor; Henderson, NV. The office telephone number is (702) 267-3385.

If you are currently **in custody**, you must contact your court-appointed attorney immediately so arrangements can be made with the Detention Center to discuss your case. If you are **out of custody**, you should contact your attorney at least **2 weeks** from today's date:

Today's Date: 6/30/2020 Defendant's Initials: [illegible]

You are responsible for maintaining contact with your court-appointed attorney. Failure to appear at your scheduled court date may result in a warrant for your arrest and/or withdrawal of your court-appointed attorney for your case.

[illegible] 6/30/2020 [illegible]

Served by / **Date** **Defendant's Signature**

Henderson Municipal Court
(702) 267-3370

WHITE – Court YELLOW – Defendant PINK – Public Defender GOLD – CAO

Revision 09/11/2017

MUNICIPAL COURT, CITY OF HENDERSON, CLARK COUNTY, NEVADA

THE CITY OF HENDERSON, NEVADA) Plaintiff)	Case No:	20CR003006
vs)		
PIEDRA, BARBARA) Defendant)	Dept. No:	2

BATTERY CONSTITUTING DOMESTIC VIOLENCE ADMONISHMENT OF RIGHTS

I am the defendant in this case. I am charged with battery constituting domestic violence in having willfully and unlawfully committed an act of force or violence upon my spouse, former spouse, a person to whom I am related by blood or marriage, a person with whom I have had or am having a dating relationship, a person with whom I have a child in common, the minor child of any of those persons, my minor child, or the custodian/legal guardian of my minor child (as defined by HMC 8.02.055 and in violation of HMC 8.02.055).

I AM AWARE THAT I HAVE EACH OF THE FOLLOWING RIGHTS AND THAT I WILL BE WAIVING THESE RIGHTS IF I PLEAD GUILTY OR NOLO CONTENDERE (NO CONTEST):

1. The right to a speedy trial;
2. The right to require the City to prove the charge(s) against me beyond a reasonable doubt;
3. The right to confront and question all witnesses against me;
4. The right to subpoena witnesses on my behalf and compel their attendance;
5. The right to remain silent and not be compelled to testify if there were a trial; and
6. The right to appeal my conviction except on constitutional or jurisdictional grounds.

I AM ALSO AWARE THAT BY PLEADING GUILTY OR NOLO CONTENDERE (NO CONTEST) I AM ADMITTING THE CITY COULD FACTUALLY PROVE THE CHARGE(S) AGAINST ME. I AM ALSO AWARE THAT MY PLEA OF GUILTY OR NOLO CONTENDERE (NO CONTEST) MAY HAVE THE FOLLOWING CONSEQUENCES:

1. I understand the City will use this conviction, and any other prior conviction from this or any other state which prohibits the same or similar conduct, to enhance the penalty for any subsequent offense;
2. I understand that, as a consequence of my plea of guilty or nolo contendere, if I am not a citizen of the United States, I may, in addition to other consequences provided by law, be removed, deported or excluded from entry into the United States or denied naturalization;
3. I understand that this conviction may affect child custody pursuant to NRS 125C.230; and
4. I understand that sentencing is entirely up to the Court and the following penalties for committing the offense described above will apply.

DEFENDANT'S INITIALS: _____

DEFENDANT'S ATTORNEY'S INITIALS (if applicable): _____

PIEDRA, BARBARA

20CR003006

BATTERY CONSTITUTING DOMESTIC VIOLENCE ADMONISHMENT OF RIGHTS (CONTINUED)

FIRST OFFENSE WITHIN 7 YEARS (MISDEMEANOR):

At least 2 days, but not more than 6 months in the Henderson Detention Center; at least 48 hours, but not more than 120 hours of community service; a fine of not less than $200.00, but not more than $1,000.00, in addition to certain fees and assessments that are required by statute; and mandatory participation in weekly counseling sessions of not less than 1 ½ hours per week, for not less than 6 months, but not more than 12 months, at my expense.

SECOND OFFENSE WITHIN 7 YEARS (MISDEMEANOR):

At least 10 days, but not more than 6 months in the Henderson Detention Center; at least 100 hours, but not more than 200 hours of community service; a fine of not less than $500.00, but not more than $1,000.00, in addition to certain fees and assessments that are required by statute and mandatory participation in weekly counseling sessions of not less than 1 ½ hours per week for 12 months, at my expense.

THIRD OFFENSE WITHIN 7 YEARS (CATEGORY B FELONY):

A category B felony punishable by a sentence of imprisonment in the Nevada State Prison for at least 1 year, but not more than 6 years; a fine of not less than $1,000, but not more than $5,000, in addition to certain fees and assessments that are required by statute; at the Court's discretion, the Court may order me to participate in an alcohol or drug treatment program at my expense; and, at the Court's discretion, if it appears from information presented to the Court that a child under the age of 18 years may need counseling as a result of the commission of a battery which constitutes domestic violence, the Court may refer the child to an agency which provides protective services, and, if that occurs, the Court will require me to reimburse the agency for the costs of any services provided, to the extent of my ability to pay. A third offense is not probationable.

SPECIAL WARNINGS: STRANGULATION, PRIOR FELONY, PREGNANT VICTIM, SUBSTANTIAL BODILY HARM

Unless a greater penalty is provided pursuant to NRS 200.481:

Strangulation - A person convicted of domestic battery committed by strangulation is guilty of a category C felony and shall be punished by imprisonment in the Nevada State Prison for at least 1 year, but not more than 5 years, and a possible fine of not more than $10,000, in addition to certain fees and assessments that are required by statute, unless a greater fine is authorized or required by statute.

Prior Felony - A person who has been previously convicted of a felony that constitutes domestic violence pursuant to NRS 33.018, or a violation of the law of any other jurisdiction that prohibits the same or similar conduct set forth in paragraph (a) of NRS 200.485, and who commits a battery which constitutes domestic violence pursuant to NRS 33.018 is guilty of a category B felony and shall be punished by imprisonment in the Nevada State Prison for at least 2 years, but not more than 15 years, and shall be further punished by a fine of not less than $2,000, but not more than $5,000, in addition to certain fees and assessments that are required by statute.

Pregnant Victim - A person convicted of a battery which constitutes domestic violence pursuant to NRS 33.018, if the battery is committed against a victim who was pregnant at the time of the battery and the person knew or should have known that the victim was pregnant, for the first offense is guilty of a gross misdemeanor; for the second or any subsequent offense, is guilty of a category B felony and shall be punished by imprisonment in the Nevada State Prison for at least 1 year, but not more than 6 years, and may be further punished by a fine of not less than $1,000, but not more than $5,000, in addition to certain fees and assessments that are required by statute.

Substantial Bodily Harm - A person convicted of a battery which constitutes domestic violence pursuant to NRS 33.018, if the battery causes substantial bodily harm, is guilty of a category B felony and shall be punished by imprisonment in the Nevada State Prison for at least 1 year, but not more than 6 years, and may be further punished by a fine of not less than $1,000, but not more than $5,000, in addition to certain fees and assessments that are required by statute.

DEFENDANT'S INITIALS: _____

DEFENDANT'S ATTORNEY'S INITIALS (if applicable): _____

PIEDRA, BARBARA 20CR003006

BATTERY CONSTITUTING DOMESTIC VIOLENCE ADMONISHMENT OF RIGHTS (CONTINUED)

ALL DEFENDANTS MUST INITIAL EITHER #1 OR #2 BELOW - DO NOT INITIAL BOTH

_____ 1. I am represented by an attorney in this case. My attorney has fully discussed these matters with me and advised me about my legal rights.
My attorney is _____, bar number: _____.

_____ 2. I have declined to have an attorney represent me and I have chosen to represent myself. I have made this decision even though there are dangers and disadvantages in self-representation in a criminal case, including, but not limited to, the following:

a) Self-representation is often unwise, and a defendant may conduct a defense to his or her own detriment;
b) A defendant who represents him/herself is responsible for knowing and complying with the same procedural rules as lawyers, and cannot expect help from the judge in complying with those procedural rules;
c) A defendant representing him/herself will not be allowed to complain on appeal about the competency or effectiveness of his or her representation;
d) The City is represented by experienced, professional attorneys who have the advantage of skill, training and ability;
e) A defendant unfamiliar with legal procedures may allow the prosecutor an advantage, may not make effective use of legal rights, and may make tactical decisions that produce unintended consequences;
f) The effectiveness of the defense may well be diminished by a defendant's dual role as attorney and accused; and
g) I understand that, as a consequence of my plea of guilty or nolo contendere, if I am not a citizen of the United States, I may, in addition to other consequences provided by law, be removed, deported or excluded from entry into the United States or denied naturalization.

_____ 08/13/1989 6/30/2020
DEFENDANT'S SIGNATURE **DEFENDANT'S DATE OF BIRTH** **DATE**

I HAVE REVIEWED THIS ADMONISHMENT WITH MY CLIENT AND AM SATISFIED THAT HE/SHE UNDERSTANDS THE RIGHTS HE/SHE IS WAIVING AND THE CONSEQUENCES OF HIS/HER PLEA OF GUILTY/NOLO CONTENDERE TO THIS DOMESTIC BATTERY CHARGE.

_____ _____
DEFENDANT'S ATTORNEY (if applicable) **BAR NUMBER**

_____
Judge, Henderson Municipal Court

6E

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Clinton Middle: Peter Last Rickman

Home Address: [redacted] S Nevada St Apt#: [redacted]

City: Carson City State: NV Zip Code: 89703

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: California Sex: ☑ M or ☐ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: _____

I am requesting registration at the following pharmacy:

Pharmacy: Walgreens Store #: 04788

Address: 1405 E. William St.

City: Carson City State: NV Zip Code: 89701

Signature of Managing Pharmacist: Anvel Lic #: NV16291 Date: 3/9/21

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☑ No ☐
2. Are you a high school graduate or the equivalent? Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☑	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation**:

	State	Date:	Case #:
Board Administrative Action:		/ /	

	State	Date:	Case #:	County	Court
Criminal Action:	NV	6/15/2018	17-CR0090	Douglas	9th Judicial District Court of the State of Nevada

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked YES to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

_____ 4-14-21

Original Signature, no copies or stamps accepted Date

Board Use Only Date Processed: _____ Amount: $50 (cc)

CASE NO. 17-CR-0090

DEPT. NO. I

FILED

2018 JUN -5 PM 3:29

BOBBIE R. WILLIAMS
CLERK

BY [illegible] DEPUTY

IN THE NINTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF DOUGLAS

THE STATE OF NEVADA,

Plaintiff,

vs

JUDGMENT OF CONVICTION

CLINTON PETER RICKMAN,

Defendant,

/

On the 25th day of July, 2017, the defendant above-named appeared before the Court with counsel, Maria Pence, Esq., and entered a plea of guilty to the crime of TRAFFICKING IN A CONTROLLED SUBSTANCE, a category B felony, in violation of NRS 453.3385, committed on or about October 13th, 2016.

On the 5th day of June, 2018, the defendant above-named appeared before the Court for sentencing with counsel, Maria Pence, Esq., and the State was represented by Deputy District Attorney Tina Russom, Esq. No sufficient legal cause was shown by the defendant as to why judgment should not be pronounced against him. The Court adjudged the defendant guilty of the crime of TRAFFICKING IN A CONTROLLED SUBSTANCE, a category B felony, in violation of NRS 453.3385.

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

The Pre-Sentence Investigation Report was amended and the Court ordered the following corrections:

1) Page 2, Under III. DEFENDANT INFORMATION, Status:, striking "Expired" and replacing it with "Valid".

The Court then sentenced the defendant to imprisonment with the Nevada Department of Corrections for a maximum term of sixty (60) months with a minimum parole eligibility of twenty-four (24) months and ordered the defendant to effect restitution in the amount of one thousand, four hundred ($1,400.00) dollars. The Court imposed a fine in the amount of five hundred ($500.00) dollars. The Court further ordered the defendant to pay the following to the District Court Clerk's Office: three dollars ($3.00) as an administrative assessment fee pursuant to NRS 176.0623(1) for obtaining and testing the genetic markers, one hundred fifty dollars ($150.00) as a fee for obtaining and testing samples of blood and saliva to determine genetic markers pursuant to NRS 176.0915(1), twenty-five dollars ($25.00) as an administrative assessment fee pursuant to NRS 176.062, and sixty dollars ($60.00) as a lab fee pursuant to NRS 453.575. Execution of this term of confinement and the imposed fine are suspended for a period not to exceed five (5) years under the general terms and conditions of the Probation Agreement and subject to the following additional special conditions:

1) the defendant shall violate no laws;

2) the defendant shall not possess any weapons;

3) the defendant is to submit his person, place of residence, vehicle or areas under his control to search at any time, with or without a search warrant or warrant of arrest, for evidence of a crime or violation of probation by the Division of Parole and Probation or its agent;

4) the defendant is to pay all court fees within ninety (90) days ($3.00 + $150.00 + $25.00 + $60.00 = $238.00);

5) the defendant is to pay restitution prior to the expiration of probation ($1,400.00).

This judgment constitutes a lien in like manner as a judgment rendered in a civil action. NRS 176.275.

The defendant is given credit for forty-four (44) days pre-sentence confinement time.

Dated this 5 day of June, 2018

NATHAN TOD YOUNG
DISTRICT JUDGE

To whom it may concern,
My name is Clinton Rickman, and in November of 2016 I was arrested for trafficking a controlled substance. My former girlfriend had asked me to help her deliver narcotics from California to Nevada, and I made the mistake of saying yes. This is the first and only time I've ever gotten in trouble with the law. Since my arrest I have been clean, completed drug and alcohol counseling, and have complied with my probationary terms. I am also an active member of Narcotics Anonymous. My restitution and Court fees are paid in full and I'm due to expire from probation in September. Thank you for taking the time to read this and consider my application.

Sincerely,
Clinton Rickman

6F

4

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: Julie Middle: _____ Last: Soneleo

Home Address: [redacted] Hatch bend ave Apt#: _____

City: North las Vegas State: NV Zip Code: 89031

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: California Sex: ☐ M or ☒ F

E-mail Address: Julie@lifecaremedicalrx.com

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: N/A

I am requesting registration at the following pharmacy:

Pharmacy: lifecare Pharmacy Store #: _____

Address: 3050 E. Desert Inn rd # 124

City: las Vegas State: NV Zip Code: 89121

Signature of Managing Pharmacist: [signature] Lic #: 10341 Date: 5/11/21

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☒ No ☐
2. Are you a high school graduate or the equivalent? Yes ☒ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked **YES** to any of the numbered questions (3-5) above, include the following information & **provide an explanation & documentation:**

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
	HI	5/3/2003	A1072341	Honolulu	Honolulu Circuit Court

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☒
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☒

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

[signature] 5/11/2021

Original Signature, no copies or stamps accepted Date

Board Use Only Date Processed: _____ Amount: 50

Darlene Nases

From: julie@lifecaremedicalrx.com
Sent: Wednesday, May 19, 2021 9:29 AM
To: Darlene Nases
Subject: RE: Pharmaceutical Technician in Training Application - Need more information

Department store in the mall in Hawaii I stole clothes that was over 250.00 that was consider felony.

On May 19, 2021 7:08 AM Darlene Nases <dnases@pharmacy.nv.gov> wrote:

Hello Julie,

One more thing. Can you please provide an explanation of what occurred with your theft?

Regards,

Darlene Nases

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Darlene Nases
Sent: Wednesday, May 19, 2021 7:06 AM
To: 'julie@lifecaremedicalrx.com' <julie@lifecaremedicalrx.com>
Subject: RE: Pharmaceutical Technician in Training Application - Need more information

Hello Julie,

This is an automatic appearance in front of the Board.

My colleague will work to add you to a meeting agenda. We are aiming for the July Board Meeting.

If you are added, you will receive a 21 day notice in the mail.

Regards,

Darlene Nases

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: julie@lifecaremedicalrx.com <julie@lifecaremedicalrx.com>
Sent: Tuesday, May 18, 2021 4:55 PM
To: Darlene Nases <dnases@pharmacy.nv.gov>
Subject: RE: Pharmaceutical Technician in Training Application - Need more information

No sorry I threw them all away. It's been so long ago.

> On May 18, 2021 4:18 PM Darlene Nases <dnases@pharmacy.nv.gov> wrote:
>
> Hello Julie,
>
> Do you have court documents?
>
> Our Deptury and Executive Secretary reviews these documents to determine if you can be licensed or if you need to appear in front of the Board.
>
> Regards,
>
> **Darlene Nases**
>
> **Licensing Specialist**
>
> **Nevada State Board of Pharmacy**

(775) 850-1440

dnases@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: julie@lifecaremedicalrx.com <julie@lifecaremedicalrx.com>
Sent: Tuesday, May 18, 2021 4:15 PM
To: Darlene Nases <dnases@pharmacy.nv.gov>
Subject: Re: Pharmaceutical Technician in Training Application - Need more information

Hello Darlene,

Sorry for the late reply. I was in meetings all day today. I am embarrassed for my actions in 2003 I was convicted as a felony in Hawaii

for Theft. This case is close I was on probation for 7 years and I was off probation early due to my good behavior. I have learn my lesson and have changed my life around ever since.

After my case was close I came back to Las Vegas this is where my family lives. I started Cosmetology school and I graduated and I do have my State board license. I also pay my student loans on time every month.

Please give me a chance to be part of Pharmacy tech trainee and I promise I will not disappoint you thank you have a wonderful evening hope to hear a positive outcome.

On May 18, 2021 11:53 AM Darlene Nases <dnases@pharmacy.nv.gov> wrote:

Hello Julie,

I received your application for Pharmaceutical Technician in Training, and I see that you marked YES in one of the questions regarding "Been charged, arrested or convicted of a felony or misdemeanor in any state".
If you can please provide an explanation of the events that occurred with your disclosure and court documents, I can attach it to your application for the our Executive and Deputy Secretary to review.

Regards,

Darlene Nases

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

Kind Regards,

Julie Sonekeo

LifeCare Medical Supplies

6415 S. Fort Apache Ste#170

Las Vegas NV 89148

Ph: 702-696-1527

Fx: 702-444-4154

The information contained in this transmission may contain privileged and confidential information, including patient information protected by federal and state privacy laws. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication is strictly prohibited. If you are not the intended

recipient, please contact the sender by reply email and destroy all copies of the original message.

Kind Regards,

Julie Sonekeo

LifeCare Medical Supplies

6415 S. Fort Apache Ste#170

Las Vegas NV 89148

Ph: 702-696-1527

Fx: 702-444-4154

The information contained in this transmission may contain privileged and confidential information, including patient information protected by federal and state privacy laws. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

Kind Regards,

Julie Sonekeo
LifeCare Medical Supplies
6415 S. Fort Apache Ste#170
Las Vegas NV 89148
Ph: 702-696-1527
Fx: 702-444-4154



The information contained in this transmission may contain privileged and confidential information, including patient information protected by federal and state privacy laws. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message.

6G

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN IN TRAINING APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Complete Name (**no abbreviations**):

First: David Middle: Vincent Last Tilsen

Home Address: [redacted] S. Grand Canyon Dr. Apt#: [redacted]

City: Las Vegas State: NV Zip Code: 89117

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Saint Paul, MN Sex: ☑ M or ☐ F

E-mail Address: [redacted]

A licensee is not required to have a Nevada State Business License, however, if you, personally, have one, please provide the number: _____

I am requesting registration at the following pharmacy:

Pharmacy: [redacted] CVS Pharmacy Store #: 02989

Address: 4755 W. Ann RD

City: Las Vegas State: NV Zip Code: 89031

Signature of Managing Pharmacist: [signature] Lic #: 20044 Date: 2/25/2021

(Without the signature of the managing pharmacist, the application will be returned.)

1. Are you 18 years of age or older? Yes ☑ No ☐
2. Are you a high school graduate or the equivalent? Yes ☑ No ☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☑	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked **YES** to any of the numbered questions (3-5) above, include the following information **& provide an explanation & documentation:** Disorderly conduct, 2012, Minneapolis, MN.

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked **YES** to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PTT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

[signature] 2/26/21

Original Signature, no copies or stamps accepted Date

Board Use Only Date Processed: _____ Amount: 50

Darlene Nases

From: REAL SPILL <[redacted]>
Sent: Saturday, April 3, 2021 9:38 AM
To: Darlene Nases
Subject: Re: Pharmaceutical Technician Application - Missing Information
Attachments: image001.jpg

Its actually quite simple, I was stopped by UofM Campus police, after leaving an event at the school. And was charged with disorderly conduct after verbally refusing to be arrested. This was nine years ago, When I was much younger. Since then I have worked on Military bases and have been told by military recruiters I am morally able to join the service.

Thank you.

On Tue, Mar 30, 2021, 7:36 AM Darlene Nases <dnases@pharmacy.nv.gov> wrote:

Hello David,

If court documents are not available, an explanation of events needs to be provided so the Board can review.

From there, the Board will decide if we can license you or if you need to appear in front of the Board.

Regards,

Darlene Nases

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

dnases@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: REAL SPILL <[redacted]>
Sent: Monday, March 29, 2021 9:30 AM
To: Darlene Nases <dnases@pharmacy.nv.gov>
Subject: Re: Pharmaceutical Technician Application - Missing Information

My phone # is 702 825 3379 and I was charged with disorderly conduct over 9 years ago. Its actually been removed from past records because of how long it has been. Thank you.

On Fri, Mar 12, 2021, 11:46 AM Darlene Nases <dnases@pharmacy.nv.gov> wrote:

Hello David,

I received your Pharmaceutical Technician in Training application, but we need more information to proceed with this request.

If you can please provide the following, I can attach it to your application.

- Telephone Number
- Since you marked "Yes" for the question, "Been charged, arrested or convicted of a felony or misdemeanor in any state".
  Could you please provide an explanation of the events that occurred and any supporting documentation? This information will be sent to our Executive Secretary and Deputy Executive Secretary for review.

Regards,

Darlene Nases

7

7A

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card only. Credit Cards are charged a 5% processing fee)

Complete Name (no abbreviations):

First: Lizbeth Middle: Last: Lara

Home Address: [redacted] Dalecrest Dr. Apt#: [redacted]

City: Las Vegas State: NV Zip Code: 89129

Telephone: [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: Torrance, CA Sex: ☐ M or ☑ F

E-mail Address: [redacted]

To qualify as a pharmaceutical technician you will need to meet one of the following criteria. Please check the appropriate box and include the required documentation.

☑ Copy of registration or on-line verification from state in which you are currently registered as a pharmaceutical technician.

☐ Copy of a certificate from an ASHP approved pharmacy technician school.

☑ Non ASHP approved school and PTCB or ICPT.

A licensee is not personally required to have a Nevada State Business License, however, if you have one, please provide the number: _____

	Yes	No
1. Are you 18 years of age or older?	☑	☐
2. Are you a high school graduate or the equivalent?	☑	☐

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☑	☐
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

	State	Date:	Case #:		
Board Administrative Action: #1	CA	1/29/2009	case # '9CP00752	Superior Court of California/Compton Courthouse	
Criminal Action:	**State**	**Date:**	**Case #:**	**County**	**Court**
#2	IA	5/17/2019	SRCR327439	Polk County	Iowa District Court for Polk County

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	☑
IF you marked YES to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Lizbeth Lara
Original Signature, no copies or stamps accepted

4/22/2021
Date

Board Use Only: Date Processed: _____ **Amount:** $50 (CC)

The following is disclosure of my previous criminal charges.

In 2009, I was charged and convicted of misdemeanor battery in violation of PC242. Conviction date 1/29/2009, case # 9CP00752 by the Superior Court of California/Compton Courthouse their address is 200 W. Compton Blvd, Compton, CA, 90220. This conviction arose out of an incident with my mother and I. I was 18 at the time of the incident, living at home with her and her new boyfriend. Her boyfriend and I didn't get along and it often caused a strife between her and myself. At the time of the incident she and I got into an argument and I left the house after her boyfriend called the police.

On 1/29/2009, my mother and I did not go to court as we were supposed to since it was a simply argument between mother and daughter, it has never turned physical. Due to me not appearing to court, the state picked up the case and since it was a family argument it was considered a battery case. I was sentenced to 24 months of probation, 52 weeks of a domestic violence program, restitution and court fees. I completed the program and paid all of my restitution and court fees and the case was dismissed pursuant to 1203.4 in July of 2013.

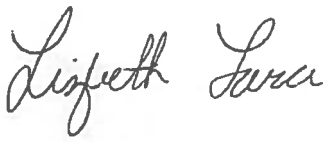
In 2012 I moved to Iowa and was offered the opportunity to go back to school where I got my high school diploma at Denison Job Corps and also completed the Pharmacy Technician program. I became certified in 2013. I began working as a Pharmacy Technician from 2013 to 2019. Unfortunately, in 2019 while in Iowa, I picked up a case for possession of a controlled substance 1st offense of methamphetamine in violation of code 124.401(5). Case # SRCR327439 by the Iowa District Court for Polk County District Court which is located on 500 Mulberry St #400, Des Moines, Iowa, 50309.

On 5/8/2019, I was arrested for having a small baggie of white crystal substance. The incident occurred after I went to my mother in laws house to try to convince my wife to come back home, my wife and I were at that time were not seeing eye to eye in our relationship. I should have just gone home instead of trying to fix my relationship that night. My mother in law called the police and I was placed under arrest after being searched. I served two weeks in Polk County Jail, I chose not to get bailed out due to remorse. I was granted a deferred judgement after pleading guilty and was given 1 year low risk probation. I also had to do a substance abuse evaluation as well as being placed on a color code, along with 50 hours of community service.

I completed all my probation requirements and paid restitution and my probationary term was successfully completed in 6 months. My case #SRCR327439 was expunged on 5/5/2020.

While completing my probation, my wife and I moved back to California. I went back to school to obtain my Medical Assistant diploma, which I completed in February of 2020. I professionally obtained three great Medical Assistant jobs while living in California. In February 2021, my wife and I settled in Las Vegas, Nevada. I will start work in May 2021 at CareNow Urgent Care where I plan on working 3 day 13 hour shifts and go to college to become a registered nurse.

I recognize that I have stumbled in my life and made irreversible choices that have led to these convictions but fortunately my life changed forever. I have been working hard to continue to stay on the path, I intend to stay on for the rest of my life. I have learned from my terrible mistakes and have built a strong support system of family and friends and continue to stay focused on my goals in life. I take full accountability of my actions. It is my goal to stay certify as a Pharmacy Technician because I have devoted so many wonderful years and it is my first great accomplishment in my life. I want to make a career of being of service to others, specifically those who are in need of any medical care. I want to keep my credentials to continue to provide everyone with the care they deserve. It is my hope that I get allowed to recertify as a Pharmacy Technician to put me on a trajectory to continue that work.



Lizbeth Lara

Iowa Board of Pharmacy

400 S.W. Eighth Street, Suite E
Des Moines, IA 50309-4688
(P): (515) 281-5944 (F): (515) 281-4609
Website: https://pharmacy.iowa.gov

CERTIFICATION OF IOWA TECHNICIAN REGISTRATION FOR THE INDIVIDUAL LISTED BELOW:

This is a primary source verification.

Name :	Lizbeth Lara
License No :	20091
License/Registration Type :	Technician
Sub Type :	Certified Technician
Date Issued :	01/01/2013
Expiration Date :	03/31/2021
Status :	Current/Active
Last Renewal Date :	04/04/2019
City :	Las Vegas
State :	NV
Certification Expiration :	05/31/2019
Address :	[redacted] Dalecrest Dr Las Vegas NV 89129
Disciplinary Action :	No

Andrew Funk, Pharm.D. , Executive Director, Iowa Board of Pharmacy. **Date:** 04/06/2021

DENISON JOB CORPS CENTER
10 Opportunity Drive
P.O. Box 610
Denison, IA 51442
Phone: (712) 265-2300
Fax: (712) 263-6910

April 12, 2021

To Whom May It Concern,

Lizbeth Lara-Esperance was a full time at the Denison Job Corps Center. While she was here she completed our Pharmacy Tech program. Her dates in that program were 8/9/12 to 3/5/13.

If you have any further questions, please call 712-265-2387.

Sincerely,

Michelle Fineran

Michelle Fineran
Records Manager

Center Information System
Denison Job Corps Center
STUDENT TRAINING ACHIEVEMENT RECORD REPORT

Student Name	Student ID
Lara-Esparza, Lizbeth	1073543

TAR Name	TAR Code	TAR Status	TAR Begin Date	TAR End Date	Staff % Completed	Student % Completed	Overall % Completed
Pharmacy Technician	PHARM-100-OJC-08	Completer	8/9/2012	3/5/2013	100%	100%	100%

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
A. Beginning as a Pharmacy Technician		3/5/2013	3/5/2013
1. Describe the duties of the pharmacy technician in accordance with individual state regulations.	3	8/16/2012	8/16/2012
2. Demonstrate knowledge of federal regulations, code of ethics and standards pertaining to the practice of pharmacy.	3	8/16/2012	8/16/2012
a. Explain the management and disposal of pharmaceutical waste, including waste considered hazardous under Environmental Protection Agency (EPA) regulations and state regulations.	3	3/5/2013	3/5/2013
3. Demonstrate knowledge of pharmaceutical, medical, and legal developments which impact on the practice of pharmacy.	3	8/16/2012	8/16/2012
a. Identify amendments to federal regulations and policies such as the Food and Drug Administrations (FDAs) disposal guidelines and the Office of National Drug Control Policys federal guidelines for proper disposal of pharmaceuticals by individuals.	3	3/5/2013	3/5/2013
4. Demonstrate knowledge of the governing boards that oversee the practice of pharmacy, including the Food and Drug Administration, Drug Enforcement Agency (DEA), state board of pharmacy, Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency for proper management of hazardous wastes and pharmaceutical wastes.	3	8/16/2012	8/16/2012
5. Discuss resources (e.g., journals, newsletters, Internet, educational conferences) for staying current with advances in pharmacy practice (e.g. automation, drug therapy, devices).	3	8/23/2012	8/24/2012
6. Demonstrate knowledge of drug information sources including electronic and printed reference material.	3	8/23/2012	8/24/2012
7. Demonstrate knowledge of practice settings missions, goals and objectives, organizational structure, and policies and procedures.	3	8/23/2012	8/24/2012
8. Explain the benefit and process of state (where mandated) and national certifications.	3	8/23/2012	8/24/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
9. Identify proper dress code for the pharmacy environment.	3	8/23/2012	8/24/2012
10. Research and document labor market information on Pharmacy Technicians in the Bureau of Labor Statistics Occupational Outlook Handbook at http://www.bls.gov/oco/ and in the Career Voyages Web site at http://www.careervoyages.gov/.	3	8/16/2012	8/16/2012
11. Identify the Pharmacy Technicians role in greening environments, sustainability, and Green Teams.	3	3/5/2013	3/5/2013
B. Basic Pharmacy Math		3/5/2013	3/5/2013
1. Demonstrate basic math skills in addition, subtraction, multiplication, and division.	3	9/17/2012	9/21/2012
2. Describe different number forms, measurement units, and mathematic operations (fractions, mixed decimals, percentages, roman numerals, commercial calculations).	3	3/5/2013	3/5/2013
3. Describe different systems of measurements (metric, English, apothecary, avoirdupois).	3	3/5/2013	3/5/2013
4. Demonstrate accurate conversion and dosage calculations used in retail pharmacy preparations.	3	3/5/2013	3/5/2013
C. Payments and Billing		10/30/2012	11/1/2012
1. Identify the customers method of payment.	3	10/30/2012	11/1/2012
2 Verify third party coverage.	3	10/30/2012	11/1/2012
3. Identify co-payment or prescriptions charge for the patient.	3	10/30/2012	11/1/2012
4. Efficiently ring up the customer for the prescription(s) and any other items.	3	10/30/2012	11/1/2012
5. Operate the cash register.	3	10/30/2012	11/1/2012
6. Make correct change.	3	10/30/2012	11/1/2012
7. Identify taxable items according to state law.	3	10/30/2012	11/1/2012
8 Determine the payment owed to the pharmacy.	3	10/30/2012	11/1/2012
D. Drugs		3/5/2013	3/5/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
1. Identify the top 100 drugs, brand and generic names.	3	3/5/2013	3/5/2013
2. Explain the term drug interaction.	3	11/13/2012	11/14/2012
3. Explain different medication routes	3	9/20/2012	9/21/2012
4. Identify medication forms.	3	9/20/2012	9/21/2012
5. Describe the requirements regarding patient package inserts.	3	11/13/2012	11/14/2012
6. Describe the concept of drug stability.	3	10/30/2012	11/1/2012
7. Describe the requirements for dispensing investigational drugs.	3	10/9/2012	10/16/2012
8 Explain the difference between controlled and non-controlled drugs and the laws pertaining to them.	3	8/16/2012	8/16/2012
9. Describe the importance of proper and timely disposal of medications including those that contain hazardous compounds listed under EPAs Resource Conservation Recovery Act (RCRA).	3	3/5/2013	3/5/2013
10. Explain when a medication becomes waste and how its management is different from management of viable medications.	3	3/5/2013	3/5/2013
11. Identify laws, regulations, and best practices related to managing and disposing of expired and waste pharmaceuticals.	3	3/5/2013	3/5/2013
E. Behind the CounterThe Prescription Process		3/5/2013	3/5/2013
1. Compare and contrast the responsibilities of the pharmacist and the pharmacy technician in the prescription process.	3	10/2/2012	10/8/2012
2. Identify the health care professionals that can write prescriptions.	3	10/2/2012	10/8/2012
3. Identify the most common symbols and abbreviations used on prescriptions, such as elemental symbols, molecular formulas, and sig codes.	3	10/2/2012	10/8/2012
a. Describe the appropriate strategies to avoid mix-ups and look-alike/ sound-alike drugs.	3	9/25/2012	10/1/2012
b. Define the elements which make up pharmaceutical terms (roots, prefixes, and suffixes)	3	9/25/2012	10/1/2012
c. Identify some of the more common roots, prefixes, and suffixes.	3	9/25/2012	10/1/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Center Information System
Denison Job Corps Center
STUDENT TRAINING ACHIEVEMENT RECORD REPORT

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
4. Explain the difference between brand and generic medication names.	3	9/25/2012	10/1/2012
5. Demonstrate knowledge of non-prescription, over-the-counter (OTC) formulations.	3	10/2/2012	10/8/2012
6. Demonstrate knowledge of monitoring systems and screening equipment (for example, blood pressure cuffs, glucose monitors).	3	11/19/2012	11/19/2012
7. Describe pharmacy software.	3	2/8/2013	2/13/2013
a. Demonstrate the ability to use pharmacy software.	3	2/8/2013	2/13/2013
b. Demonstrate the ability to access a customers file, obtain the price of a product, print a label, and print a customers history.	3	2/8/2013	2/13/2013
8. Demonstrate the ability to accurately receive and screen prescription/medication orders, and demonstrate the following tasks:	3	2/8/2013	2/13/2013
a. Use first person and electronic systems to receive prescription/medication orders.	3	2/8/2013	2/13/2013
b. Interview with customers, their representatives, or caregivers to efficiently and accurately collect customer information.	3	2/8/2013	2/13/2013
c. Collect information from the medical chart, customer profile, or medical record for use by the pharmacist.	3	2/8/2013	2/13/2013
d. Accurately create a new customer profile or enter data into an existing profile.	3	2/8/2013	2/13/2013
e. Accurately and efficiently access a prescription/medication order for completeness.	3	2/8/2013	2/13/2013
f. Identify and list the information required on completed prescription forms.	3	2/8/2013	2/13/2013
g. Gather information missing from the prescription form.	3	2/8/2013	2/13/2013
h Describe the process and benefits of a paperless prescribing system.	3	3/5/2013	3/5/2013
(1) Identify the states requirements and the technicians role in the paperless prescribing system.	3	3/5/2013	3/5/2013
9. Demonstrate the ability to follow the established procedure to generate accurate and complete product labels.	3	10/9/2012	10/16/2012
10. Demonstrate knowledge of state-specific prescription transfer regulations.	3	10/2/2012	10/8/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

FOR OFFICIAL USE ONLY

Center Information System
Denison Job Corps Center
STUDENT TRAINING ACHIEVEMENT RECORD REPORT

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
11. Demonstrate knowledge of formula to verify the validity of a prescribers DEA number.	3	10/2/2012	10/8/2012
12. Demonstrate knowledge of techniques for detecting forged or altered prescriptions.	3	11/13/2012	11/14/2012
13. Demonstrate knowledge of techniques for detecting prescription errors (for example, abnormal doses, early refill, incorrect quantity, incorrect patient ID number, and incorrect drug).	3	11/13/2012	11/14/2012
14. Determine proper procedures used in the preparation of medications and demonstrate the following tasks:	3	11/13/2012	11/14/2012
a. Follow established laws and protocols to select appropriate product.	3	1/28/2013	1/28/2013
b. Describe National Drug Code (NDC) number components.	3	10/2/2012	10/8/2012
c. Describe the purpose of lot numbers and expiration dates.	3	10/30/2012	11/1/2012
(1) Demonstrate efficiency in distributing older inventory first to avoid pharmaceutical waste.	3	3/5/2013	3/5/2013
d. Obtain prescribed medications from inventory.	3	3/5/2013	3/5/2013
e. Count and measure finished dosage forms as specified by prescription medication order using proper counting techniques.	3	9/20/2012	9/21/2012
f. Package products in the appropriate type and size of container using a manual process or automated process.	3	9/20/2012	9/21/2012
g. Describe storage requirements	3	10/30/2012	11/1/2012
h. Follow established policies and procedures for recording the preparation of bulk, unit dose, controlled substances, and special doses of medication prepared for immediate or future use.	3	2/8/2013	2/13/2013
15. Demonstrate the ability to distribute medication, and complete the following tasks	3	2/8/2013	2/13/2013
a. Affix the appropriate primary and auxiliary labels to containers.	3	2/8/2013	2/13/2013
b. Follow protocol for assembling appropriate customer information materials.	3	2/8/2013	2/13/2013
c. Deliver correct medication, equipment, devices, or supplies to the pharmacist for verification.	3	2/8/2013	2/13/2013
16. Explain alternative strategies for securing pharmacy items that are not available.	3	2/8/2013	2/13/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
17. Explain acceptable methods for communicating changes in products availability to customers, caregivers, and/or health care professionals.	3	2/8/2013	2/13/2013
18. Explain techniques of assessing patients compliance with prescription medication orders.	3	2/8/2013	2/13/2013
19. Describe the action to be taken in the event of a missed dose.	3	2/8/2013	2/13/2013
20. Demonstrate appropriate filing methods for the following:	3	8/16/2012	8/16/2012
a. Prescription, non-controlled	3	8/16/2012	8/16/2012
b. Prescription, controlled	3	8/16/2012	8/16/2012
c. Prescription, Schedule II Controlled Substance (CII)	3	8/16/2012	8/16/2012
21. Demonstrate knowledge of quality improvement programs in order to decrease dispensing incidents.	3	10/9/2012	10/16/2012
F. Customer Service Within the Retail Pharmacy Setting		1/28/2013	1/28/2013
1. Adhere to legal and ethical guidelines for safeguarding the confidentiality of patient information:	3	8/16/2012	8/16/2012
a. Demonstrate an understanding of Health Insurance Portability and Accountability Act (HIPAA) compliance and Protected Health Information (PHI) regarding privacy of records.	3	8/16/2012	8/16/2012
b. Describe local and online opportunities to become certified in HIPAA guidelines.	3	8/16/2012	8/16/2012
c. Explain the legal requirements for pharmacist counseling of patients or a patients representative.	3	8/16/2012	8/16/2012
2. Identify ways to show compassion for special needs of customers and caregivers when delivering pharmacy services.	3	10/9/2012	10/16/2012
3. Demonstrate effective strategies for communicating with patients and caregivers who are non-English speakers, or who are impaired, e.g. blind, deaf, illiterate, and/or cognitive impaired.	3	10/9/2012	10/16/2012
4. Identify ways to show respect for caregivers when delivering pharmacy services.	3	10/9/2012	10/16/2012
5. Describe some typical adaptations made in pharmaceutical care plans to accommodate patients of diverse cultural backgrounds	3	10/9/2012	10/16/2012
6. Demonstrate the proper phone procedures for the following tasks	3	10/9/2012	10/16/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
a. Placing and receiving calls to/from a doctors office:	3	8/23/2012	8/24/2012
I Refill prescriptions	3	8/23/2012	8/24/2012
Ii. New prescriptions	3	8/23/2012	8/24/2012
b. Receive calls from customers:	3	8/23/2012	8/24/2012
i. Prescription/medication calls handled by the pharmacy technician	3	8/23/2012	8/24/2012
Ii. Prescription/medication calls handled by the pharmacist	3	8/23/2012	8/24/2012
c Placing and receiving calls to/from an insurance provider (third party).	3	1/28/2013	1/28/2013
G. Inventory Management		2/8/2013	2/13/2013
1. Describe the procedures for ordering pharmaceuticals, durable medical equipment devices, and supplies.	3	10/30/2012	11/1/2012
2. Describe the various methods of inventory control (e.g., perpetual, point of sale, etc).	3	10/30/2012	11/1/2012
3. Describe established methods for receiving orders.	3	10/30/2012	11/1/2012
4. Describe the policy and procedures to maintain record of controlled substances received, stored, and removed from inventory.	3	10/30/2012	11/1/2012
5. Demonstrate the ability to place pharmaceuticals, durable medical equipment, devices, and supplies in inventory under proper storage conditions	3	2/8/2013	2/13/2013
6. Demonstrate the ability to properly remove from inventory, expired/discontinued pharmaceuticals, durable medical equipment, devices, supplies or recalled items, using appropriate documentation.	3	2/8/2013	2/13/2013
7. Describe established policies and procedures to deter theft and/or drug diversion.	3	1/28/2013	1/28/2013
8. Identify the FDAs classifications of recalls.	3	1/28/2013	1/28/2013
9. Describe established policies and procedures to maintain a record of repackaging, recalls, and return of pharmaceutical, durable medical equipment, devices, and supplies.	3	1/28/2013	1/28/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Center Information System
Denison Job Corps Center
STUDENT TRAINING ACHIEVEMENT RECORD REPORT

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
10. Demonstrate written, oral, and electronic communication channels necessary to ensure appropriate follow-up and problem resolution (for example, product recalls, supplier shorts).	3	1/28/2013	1/28/2013
11. Describe the quality assurance policies, procedures, and practices for inventory control systems.	3	1/28/2013	1/28/2013
12. Demonstrate appropriate filing methods in the following areas.	3	11/13/2012	11/14/2012
a. Receiving records, non-controlled.	3	11/13/2012	11/14/2012
b. Receiving records, controlled.	3	11/13/2012	11/14/2012
c. Receiving records, CII.	3	11/13/2012	11/14/2012
H. Body Systems, Drugs, and Common Diseases		3/5/2013	3/5/2013
1. For each of the following systems explain the body system; describe usage of common prescription and non-prescription drugs used to treat related diseases, identify (list) commonly used drugs for treating each of the systems and conditions (generic and brand names); identify side effects; and identify the interactions of drugs.			
a. Cardiovascular system	3	12/19/2012	1/15/2013
b. Respiratory system	3	11/29/2012	11/30/2012
c. Gastrointestinal system	3	12/11/2012	12/11/2012
d. Renal system	3	12/19/2012	1/15/2013
e. Nervous system	3	11/29/2012	11/30/2012
f. Endocrine system	3	11/19/2012	11/19/2012
(1) Describe the possible impacts of different chemicals on the endocrine system (pharmaceuticals and personal care products, cleaning products, pesticides, etc.).	3	3/5/2013	3/5/2013
g. Reproductive system	3	1/10/2013	1/15/2013
h. Immune system	3	2/7/2013	2/7/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
i. Skeletal system (bones and joints)	3	11/19/2012	11/19/2012
j. Eyes, ears, nose and throat	3	11/29/2012	11/30/2012
k. Dermatologic	3	12/11/2012	12/11/2012
l. Hematologic	3	12/19/2012	1/15/2013
m. Muscular system	3	11/19/2012	11/19/2012
n. Psychosomatic/Psychosocial	3	11/29/2012	11/30/2012
o. Pain management	3	2/1/2013	2/7/2013
2. Explain the difference between therapeutic response, side effects, and toxicities.	3	11/13/2012	11/14/2012
3. Demonstrate knowledge of epidemiology.	3	11/13/2012	11/14/2012
4. Demonstrate knowledge of standard and abnormal lab values.	3	10/2/2012	10/8/2012
I. Hospital Math		3/5/2013	3/5/2013
1. Demonstrate the use of ratio and proportion:	3	3/5/2013	3/5/2013
a. Intravenous flow rates	3	3/5/2013	3/5/2013
b. Allegations	3	3/5/2013	3/5/2013
c. Temperature conversions	3	3/5/2013	3/5/2013
d. Childrens dosage (Clarks rule, Youngs rule)	3	3/5/2013	3/5/2013
e. Dilutions and concentrations	3	3/5/2013	3/5/2013
2. Explain the techniques for preparing the following:			

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
a. Solutions	3	11/7/2012	11/14/2012
b. Suspensions	3	11/7/2012	11/14/2012
c. Elixirs	3	11/7/2012	11/14/2012
d. Emulsions	3	11/7/2012	11/14/2012
e. Extracts	3	11/7/2012	11/14/2012
J. Hospital Compounding		1/28/2013	1/28/2013
1. Describe proper procedures used in the preparation of medication.	3	10/22/2012	10/25/2012
2. Describe basic compounding equipment.	3	10/22/2012	10/25/2012
3. Describe the process of compounding non-sterile products	3	10/22/2012	10/25/2012
a. Topical dosage forms	3	10/22/2012	10/25/2012
b. Oral dosage forms	3	10/22/2012	10/25/2012
c. Ear Drops	3	10/22/2012	10/25/2012
4 Describe the process for compounding sterile-products:	3	10/22/2012	10/25/2012
a. IV admixtures	3	10/22/2012	10/25/2012
b Chemotherapy	3	10/22/2012	10/25/2012
c. Total Parenteral Nutrition (TPN) solutions	3	10/22/2012	10/25/2012
d. Reconstituted injectable and non-injectable medications	3	10/22/2012	10/25/2012
e. Injectables	3	10/22/2012	10/25/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
f. Radio pharmaceuticals	3	10/22/2012	10/25/2012
g. Eye drops	3	10/22/2012	10/25/2012
5. Describe how to determine the correct amount of ingredients for a compound product.	3	1/28/2013	1/28/2013
6. Demonstrate knowledge of physical and chemical incompatibilities.	3	1/28/2013	1/28/2013
7. Demonstrate using and calibrating a scale.	3	1/28/2013	1/28/2013
8. Demonstrate proper documentation techniques.	3	1/28/2013	1/28/2013
K. Hospital Pharmacy Equipment and Procedures		3/5/2013	3/5/2013
1. Describe governing boards that oversee hospital pharmacy	3	10/22/2012	10/25/2012
2 Describe the laws pertaining to compounding and manufacturing.	3	10/22/2012	10/25/2012
3. Describe the policies and procedures for the following:			
a. Hazardous and medical waste management (e.g., needles, bodily fluid, pharmaceuticals regulated under RCRA and similar pharmaceuticals, other toxic materials)	3	3/6/2013	3/6/2013
b. Sanitation management	3	3/5/2013	3/5/2013
c. Infection control	3	3/5/2013	3/5/2013
4. Describe established procedures for cleaning a laminar flow hood.	3	10/22/2012	10/25/2012
5. Demonstrate knowledge of techniques, equipment, and supplies for drug administration (for example, insulin syringes and IV tubing).	3	10/22/2012	10/25/2012
a. Describe alternatives to PVC/DEHP tubing to minimize impact on the environment.	3	3/5/2013	3/5/2013
6. Demonstrate knowledge of medical and surgical appliances and devices (i.e., ostomies, orthopedic devices, pumps).	3	10/30/2012	11/1/2012
7. Demonstrate the ability to use and properly clean a counting tray and spatula, mortar and pestle, and water dispensing system.	3	10/22/2012	10/25/2012

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
8. Demonstrate the ability to maintain a clean work environment.	3	10/22/2012	10/25/2012
9. Demonstrate knowledge of delivery systems used within a hospital setting (for example, pneumatic tube, and robot).	3	10/22/2012	10/25/2012
10. Demonstrate knowledge of automatic stop orders and restricted medication orders.	3	1/28/2013	1/28/2013
11. Demonstrate knowledge of bar coding, nursing stations, and crash carts.	3	10/9/2012	10/16/2012
L. Pharmacy Administration		2/7/2013	2/7/2013
1. Demonstrate knowledge of requirements for mailing medications.	3	8/23/2012	8/24/2012
2. Describe lines of communication within the pharmacy setting.	3	8/23/2012	8/24/2012
3. Describe the principles of resource allocation (i.e., scheduling, cross-training and work flow).	3	8/23/2012	8/24/2012
4. Describe productivity, efficiency, and customer service satisfaction measures.	3	8/23/2012	8/24/2012
5. Demonstrate knowledge of different written, oral and electronic communication systems (i.e., internet, inter office mail, fax).	3	8/23/2012	8/24/2012
6. Demonstrate knowledge of legal and regulatory requirements for personnel, facilities, equipment, and supplies (for example, space requirements, prescription file storage, cleanliness, reference materials, and storage of radiopharmaceuticals).	3	8/23/2012	8/24/2012
7. Describe storage requirements and expiration dates for equipment and supplies (for example, first aid items and fire extinguishers).	3	8/23/2012	8/24/2012
8. Describe different types of security systems for the protection of employees, customers, and property.	3	8/23/2012	8/24/2012
9. Explain the Americans with Disabilities Act.	3	1/28/2013	1/28/2013
10. Explain security procedures related to data integrity, security, and confidentiality.	3	10/9/2012	10/16/2012
11. Describe downtime backup procedures.	3	10/9/2012	10/16/2012
12. Describe archiving, including legal requirements for archiving.	3	10/9/2012	10/16/2012
13. Demonstrate the ability to complete an employee evaluation form and describe staff training techniques.	3	2/7/2013	2/7/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

Training Achievement Record Items	Rating	Proficiency Attained	Student Acknowledgement
14. Describe the required operational licenses and certificates.	3	10/9/2012	10/16/2012
M. Industry Vocabulary		2/7/2013	2/7/2013
1. Define and use technical words and phrases relevant to pharmacy technician.	3	2/7/2013	2/7/2013

Instructor Signature: Electronically signed by Terri Durston on 3/5/2013

Manager Signature: Electronically signed by Terri Mohr on 3/6/2013

Rating : 1 - Exposed/not proficient; 2 - Proficient; 3 - Proficient and can teach others

Student Name: Lara-Esparza, Lizbeth
Student ID 1073543

PHARMACY TECHNICIAN CERTIFICATION BOARD

certifies that

Lizbeth Lara

has met all requirements for certification and merits the designation of

Certified Pharmacy Technician (CPhT)

Certification Number	Initial Certification Date	Application Deadline	Expiration Date
10004172	March 21, 2013	May 01, 2023	May 31, 2023

PTCB
Pharmacy Technician Certification Board

Meghan D. Swarthout
President, Certification Council

William Schmidt
Executive Director, CEO

Verify certification at **ptcb.org**.

1670

MINUTE ORDER
SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

DATE PRINTED: 07/23/13

CASE NO. 9CP00752

THE PEOPLE OF THE STATE OF CALIFORNIA
VS.
DEFENDANT 01: LIZBETH LARA

BAIL: APPEARANCE DATE	AMOUNT OF BAIL	DATE POSTED	RECEIPT OR BOND NO.	SURETY COMPANY	REGISTER NUMBER

CASE FILED ON 01/21/09.

COMPLAINT FILED, DECLARED OR SWORN TO CHARGING DEFENDANT WITH HAVING COMMITTED, ON OR ABOUT 11/29/08 IN THE COUNTY OF LOS ANGELES, THE FOLLOWING OFFENSE(S) OF:

COUNT 01: 242 PC MISD

ON 07/12/13 AT 900 AM IN COMPTON COURTHOUSE DEPT 006

CASE CALLED FOR MOTN/DISM PURSNT PC SEC 1203.4

PARTIES: SEAN D. COEN (JUDGE) NONE (CLERK)
NONE (REP) NONE ()

DEFENDANT IS NOT PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL

AS TO COUNT (01):

MOTION PURSUANT TO SECTION 1203.4/1203.4A OF THE CALIFORNIA PENAL CODE IS HEREBY GRANTED. IT IS HEREBY ORDERED THAT THE PLEA, VERDICT, OR FINDING OF GUILT BE SET ASIDE AND VACATED AND A PLEA OF NOT GUILTY BE ENTERED; AND THAT THE COMPLAINT BE, AND IS HEREBY DISMISSED

COUNT (01): IS DISMISSED: DISMISSED PER 1203.4 P.C.

COURT ORDERS AND FINDINGS:

MOTION PURSUANT TO 1203.4 OR 1203.4A PENAL CODE GRANTED.

PROCESSING COST PAID UNDER RECEIPT #COMS05499005 IN THE AMOUNT OF $120.00 ON 6-04-13.

COUNT (01): DISPOSITION: DISMISSED PER 1203.4 P.C.

DMV ABSTRACT NOT REQUIRED

CASE NO. 9CP00752
DEF NO. 01

DATE PRINTED 07/23/13

NEXT SCHEDULED EVENT:
DISMISSD PURSUANT TO 1203.4 PC

NEXT SCHEDULED EVENT:

PROCEEDINGS TERMINATED

07/23/13

I HEREBY CERTIFY THIS TO BE A TRUE AND CORRECT COPY OF THE ELECTRONIC MINUTE ORDER ON FILE IN THIS OFFICE AS OF THE ABOVE DATE.

JOHN A. CLARKE , EXECUTIVE OFFICER/CLERK OF SUPERIOR COURT, COUNTY OF LOS ANGELES, STATE OF CALIFORNIA

BY _____, DEPUTY

SUPERIOR COURT, LOS ANGELES COUNTY • CALIFORNIA •

MOTN/DISM PURSNT PC SEC 1203.4
HEARING DATE: 07/12/13

CR-181

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address)	FOR COURT USE ONLY
TELEPHONE NO.: [redacted] FAX NO. (Optional): [redacted] E-MAIL ADDRESS (Optional): [redacted] ATTORNEY FOR (Name):	FILED LOS ANGELES SUPERIOR COURT JUL 12 2013 JOHN A. CLARKE, EXECUTIVE OFFICER/CLERK BY [signature] DEPUTY
PEOPLE OF THE STATE OF CALIFORNIA v. DEFENDANT: Lizbeth Lara	CASE NUMBER: 9CP00752
ORDER FOR DISMISSAL (Pen. Code, §§ 17, 1203.4, 1203.4a)	
DEFENDANT'S INFORMATION CII: DRIVER'S LIC #: [redacted] SSN # (LAST FOUR DIGITS ONLY): [redacted] DATE OF BIRTH: [redacted]	

☐ The court denies the petition.

☑ The court grants the petition. The court finds from the records on file in this case, and from the foregoing petition, that the defendant is eligible for the relief requested.

☐ The court reduces the felony offense to a misdemeanor.

☐ It is ordered that the plea, verdict, or finding of guilt in the above-entitled action be set aside and vacated and a plea of not guilty be entered and that the complaint be, and is hereby, dismissed. If this order is granted under the provisions of Penal Code section 1203.4, the defendant is required to disclose the above conviction in response to any direct question contained in any questionnaire or application for public office or for licensure by any state or local agency, or for contracting with the California State Lottery. Further, if this order is granted under the provisions of Penal Code section 1203.4, the defendant may also be eligible to obtain a certificate of rehabilitation and pardon under the procedure set forth in Penal Code section 4852.01 et seq.

☐ If the order is granted under the provisions of either Penal Code section 1203.4 or 1203.4a, the defendant is released from all penalties and disabilities resulting from the offense except as provided in Penal Code sections 12021 and 12021.1 and Vehicle Code section 13555. The dismissal does not permit a person to own, possess, or have in his or her control a firearm if prevented by Penal Code sections 12021 or 12021.1. In addition, as required by Penal Code section 299(f), relief under Penal Code sections 17, 1203.4, or 1203.4a does *not* release defendant from the separate administrative duty to provide specimens, samples, or print impressions under the DNA and Forensic Identification Database and Data Bank Act (Pen. Code, § 295 et seq.) if defendant was found guilty by a trier of fact, not guilty by reason of insanity, or pled no contest to a qualifying offense as defined in Penal Code section 296(a).

Date: 7/12/13

[signature]
(JUDICIAL OFFICER)

SEAN D. COEN

SUPERIOR COURT OF CALIFORNIA LOS ANGELES COUNTY FOR COURT USE ONLY

Form Approved for Optional Use
Judicial Council of California
CR-181 [New January 1, 2009]

ORDER FOR DISMISSAL

Penal Code, §§ 17, 1203.4, and 1203.4a
www.courtinfo.ca.gov
American LegalNet, Inc.
www.FormsWorkflow.com

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address)

TELEPHONE NO.: [redacted] FAX NO. (Optional):
E-MAIL ADDRESS (Optional):
ATTORNEY FOR (Name):

FOR COURT USE ONLY

CR-180

PEOPLE OF THE STATE OF CALIFORNIA
v.
DEFENDANT:
Lizbeth Lara

PETITION FOR DISMISSAL
(Pen. Code, §§ 17, 1203.4, 1203.4a)

CASE NUMBER: 9CP00752

RECEIVED
LOS ANGELES SUPERIOR COURT
JUN .. 2013
JOHN A. CLARKE, CLERK
BY DEPUTY

DEFENDANT'S INFORMATION
CII: [redacted]
DRIVER'S LIC #: [redacted]
SSN # (LAST FOUR DIGITS ONLY): [redacted]
DATE OF BIRTH: [redacted]

1. On (*date*): 6/15/09 the defendant in the above-entitled criminal action was convicted of a violation of section(s) (*specify*): 242 of the (*specify*): Penal Code.
2. The offense was a ☑ misdemeanor ☐ felony.
   Felony offense (*Pen. Code, § 17*):
   ☐ The offense listed above is a felony that may be reduced to a misdemeanor under Penal Code section 17.
3. ☑ Offense with probation granted (*Pen. Code, § 1203.4*):
   Probation was granted on the terms and conditions set forth in the docket of the above-entitled court; the defendant is not serving a sentence for any offense, nor on probation for any offense, nor under charge of commission of any crime, and the defendant (*check one*):
   a. ☑ has fulfilled the conditions of probation for the entire period thereof;
   b. ☐ has been discharged from probation prior to the termination of the period thereof; or
   c. ☐ should be granted relief in the interests of justice. (*Please note: You must explain why granting a dismissal would be in the interests of justice by completing and attaching the optional* Attached Declaration (*form MC-031*).)
4. ☐ Offense with sentence other than probation (*Pen. Code, § 1203.4a*):
   ☐ Probation was not granted; more than one year has elapsed since the date of pronouncement of judgment. The defendant has complied with the sentence of the court and is not serving a sentence for any offense nor under charge of commission of any crime, and since said pronouncement of judgment has lived an honest and upright life and conformed to and obeyed the laws of the land.

Petitioner requests that defendant be permitted to withdraw the plea of guilty, or that the verdict or finding of guilt be set aside and a plea of not guilty be entered and the court dismiss this action under section ☑ 1203.4 or ☐ 1203.4a of the Penal Code.

☐ Petitioner requests that the felony charge be reduced to a misdemeanor under Penal Code section 17.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on: 6/7/13 (DATE)

▶ Lizbeth Lara (SIGNATURE OF PETITIONER OR ATTORNEY)

1504 11th Street (ADDRESS, DEFENDANT)

Des Moines (CITY) IA (STATE) 50314 (ZIP CODE)

RECEIPT #: CONSOS47005
DATE PAID: 06/07/13
PAYMENT: $120.00
RECEIVED:
CHECK:
CASH:
CHANGE:
FEE:
LEAVE:

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

NO. 9CP00752 PAGE NO. 1
THE PEOPLE OF THE STATE OF CALIFORNIA VS. CURRENT DATE 06/03/13
DEFENDANT 01: LIZBETH LARA
LAW ENFORCEMENT AGENCY EFFECTING ARREST: LASD - COMPTON STATION PATROL

BAIL: APPEARANCE DATE	AMOUNT OF BAIL	DATE POSTED	RECEIPT OR BOND NO.	SURETY COMPANY	REGISTER NUMBER

CASE FILED ON 01/21/09.
COMPLAINT FILED, DECLARED OR SWORN TO CHARGING DEFENDANT WITH HAVING COMMITTED, ON OR ABOUT 11/29/08 IN THE COUNTY OF LOS ANGELES, THE FOLLOWING OFFENSE(S) OF:
COUNT 01: 242 PC MISD
NEXT SCHEDULED EVENT:
01/29/09 830 AM ARRAIGNMENT DIST COMPTON COURTHOUSE DEPT 010

ON 01/29/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR ARRAIGNMENT
PARTIES: PAT CONNOLLY (JUDGE) JAN ULIBARRI (CLERK)
KAREN DIX (REP) WYATT BLOOMFIELD (DA)
THE DEFENDANT FAILS TO APPEAR, WITHOUT SUFFICIENT EXCUSE AND NOT REPRESENTED BY COUNSEL
A BENCH WARRANT IS ORDERED FOR THE DEFENDANT'S FAILURE TO APPEAR AT HEARING.
NEXT SCHEDULED EVENT:
BENCH/WARRANT ISSUED

01/29/09 BENCH WARRANT IN THE AMOUNT OF $30,000.00 BY ORDER OF JUDGE PAT CONNOLLY ISSUED. (02/05/09).

ON 03/24/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 001

CASE CALLED FOR ARRAIGNMENT
PARTIES: COMR. MICHAEL KAUTZ (JUDGE) RON DRABOS (CLERK)
BARBARA B. GIBBONS (REP) LORI L. GRAY (DA)

DEFENDANT DEMANDS COUNSEL.
COURT REFERS DEFENDANT TO THE PUBLIC DEFENDER.
PUBLIC DEFENDER APPOINTED. THOMAS S. BRUNER - P.D.
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY THOMAS S. BRUNER DEPUTY PUBLIC DEFENDER
DEFENDANT STATES HIS/HER TRUE NAME AS CHARGED.
DEFENDANT WAIVES ARRAIGNMENT, READING OF COMPLAINT, AND STATEMENT OF CONSTITUTIONAL AND STATUTORY RIGHTS.
DEFENDANT WAIVES FURTHER ARRAIGNMENT.
DEFENDANT PLEADS NOT GUILTY TO COUNT 01, 242 PC.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
A PROTECTIVE ORDER IS SIGNED AND FILED WITH THE COURT THIS DATE PROTECTING: BLANCA LARA AS MORE FULLY REFLECTED IN THE NOTES OF THE OFFICIAL COURT REPORTER INCORPORATED HEREIN BY REFERNCE.

CASE NO. 9CP00752 PAGE NO. 2
DEF NO. 01 DATE PRINTED 06/03/13

.
AS A CONDITION OF O.R. RELEASE, THE DEFENDANT IS ORDERED TO
COMPLY WITH ALL TERMS AND CONDITIONS OF THE PROTECTIVE ORDER.
.
ORDER FOR RELEASE ISSUED # AK557627.
NEXT SCHEDULED EVENT:
04/07/09 830 AM PRETRIAL HEARING DIST COMPTON COURTHOUSE DEPT 010
NEXT SCHEDULED EVENT :
04/21/09 830 AM JURY TRIAL DIST COMPTON COURTHOUSE DEPT 010
DAY 28 OF 30

03/24/09 BENCH WARRANT IN THE AMOUNT OF $30,000.00 RECALLED. (03/24/09).

CUSTODY STATUS: RELEASED ON OWN RECOGNIZANCE

ON 04/07/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR PRETRIAL HEARING
PARTIES: PAT CONNOLLY (JUDGE) STACY RUCKER (CLERK)
LISA RODRIGUEZ (REP) EUGENE K.CHONG (DA)
THE DEFENDANT FAILS TO APPEAR, WITHOUT SUFFICIENT EXCUSE AND REPRESENTED BY
BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER
THE COURT ORDERS A BENCH WARRANT TO BE ISSUED. BAIL SET
$30,000.
NEXT SCHEDULED EVENT:
BENCH/WARRANT TO ISSUE

04/07/09 BENCH WARRANT IN THE AMOUNT OF $30,000.00 BY ORDER OF JUDGE PAT
CONNOLLY ISSUED. (04/07/09).

ON 06/12/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR BENCH WARRANT HEARING
PARTIES: RICARDO R. OCAMPO (JUDGE) STACY RUCKER (CLERK)
KAREN DIX (REP) REENA AJIT DESAI (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC

DEFENDER
BAIL SET AT $30,000
BENCH WARRANT IS RECALLED AND QUASHED.
DEFENDANT'S MOTION TO BE RELEASED ON HER OWN RECOGNIZANCE OR IN
THE ALTERNATIVE TO REDUCE BAIL IS DENIED.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
UPON MOTION OF DEFENDANT
06/15/09 830 AM PRETRIAL HEARING DIST COMPTON COURTHOUSE DEPT 010
NEXT SCHEDULED EVENT:
07/10/09 830 AM JURY TRIAL DIST COMPTON COURTHOUSE DEPT 010
DAY 28 OF 30

06/12/09 BENCH WARRANT IN THE AMOUNT OF $30,000.00 RECALLED. (06/12/09).

CUSTODY STATUS: REMANDED TO CUSTODY

CASE NO. 9CP00752 PAGE NO. 3
DEF NO. 01 DATE PRINTED 06/03/13

ON 06/15/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR PRETRIAL HEARING
PARTIES: PAT CONNOLLY (JUDGE) STACY RUCKER (CLERK)
KAREN DIX (REP) PAUL A. THOMPSON (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER

DEFENDANT ADVISED OF THE FOLLOWING RIGHTS ORALLY:
DEFENDANT ADVISED OF THE FOLLOWING RIGHTS IN WRITING:
THE RIGHT TO BE REPRESENTED BY A LAWYER AT ALL STAGES OF THE PROCEEDINGS, INCLUDING THE RIGHT, IF QUALIFIED, TO BE REPRESENTED BY A LAWYER AT PUBLIC EXPENSE;
THE RIGHT TO REPRESENT YOURSELF, IF YOU KNOWINGLY, INTELLIGENTLY, UNDERSTANDINGLY, AND EXPLICITLY WAIVE YOUR RIGHT TO A LAWYER AND UNDERSTAND THE DANGERS AND DISADVANTAGES OF SELF-REPRESENTATION; THE RIGHT TO A

REASONABLE CONTINUANCE BEFORE ENTERING A PLEA;
YOU MAY PLEAD GUILTY, NOT GUILTY OR, WITH THE CONCURRENCE OF THE COURT, NOLO CONTENDERE TO THE CHARGES IN THE COMPLAINT;
A PLEA OF NOLO CONTENDERE SHALL BE CONSIDERED THE SAME AS A PLEA OF GUILTY. FOR THE PURPOSES OF THE CRIMINAL PROCEEDING, IT IS AN ADMISSION OF GUILT BUT CANNOT BE USED AGAINST YOU AS AN ADMISSION OF FAULT IN A CIVIL PROCEEDINGS ARISING OUT OF THE INCIDENT THAT CAUSED CRIMINAL PROCEEDINGS TO BE BROUGHT;
IF YOU PLEAD NOT GUILTY, YOU ARE ENTITLED TO A SPEEDY AND PUBLIC TRIAL;
YOU HAVE A RIGHT TO BE TRIED WITHIN 30 DAYS FROM THE DATE OF ARRAIGNMENT IF IN CUSTODY: 45 DAYS IF NOT IN CUSTODY;
THE CASE WILL BE DISMISSED IF NOT HEARD WITHIN THE STATUTORY TIME, UNLESS GOOD CAUSE FOR A DELAY IS SHOWN;
THE RIGHT TO BE CONFRONTED BY AND TO CROSS-EXAMINE WITNESSES WHO TESTIFY AGAINST YOU AND THE RIGHT TO HAVE WITNESSES SUBPOENAED INTO COURT TO TESTIFY IN YOUR DEFENSE AT NO COST TO YOU;
THE RIGHT NOT TO TESTIFY IN YOUR CASE; AND THE RIGHT TO TESTIFY IN YOUR CASE IF YOU WISH;
IF YOU PLEAD GUILTY, NOLO CONTENDERE OR ARE CONVICTED AFTER A TRIAL, YOU HAVE A RIGHT TO A REASONABLE CONTINUANCE BEFORE SENTENCE IS IMPOSED, TO WIT: NOT LESS THAN 6 HOURS, NOR MORE THAN 5 DAYS;
THE RIGHT TO BE RELEASED UPON POSTING OF A REASONABLE BAIL IN AN AMOUNT TO BE

FIXED BY THE COURT;
YOU ARE ADVISED OF THE PROVISIONS OF SECTION 1203.4 OF THE PENAL CODE;

DEFENDANT ADVISED OF AND PERSONALLY AND EXPLICITLY WAIVES THE FOLLOWING RIGHTS:
WRITTEN ADVISEMENT OF RIGHTS AND WAIVERS FILED, INCORPORATED BY REFERENCE HEREIN
TRIAL BY COURT AND TRIAL BY JURY
CONFRONTATION AND CROSS-EXAMINATION OF WITNESSES;
SUBPOENA OF WITNESSES INTO COURT TO TESTIFY IN YOUR DEFENSE;
AGAINST SELF-INCRIMINATION;
DEFENDANT ADVISED OF THE FOLLOWING:
THE NATURE OF THE CHARGES AGAINST HIM, THE ELEMENTS OF THE OFFENSE IN THE COMPLAINT, AND POSSIBLE DEFENSES TO SUCH CHARGES;
THE POSSIBLE CONSEQUENCES OF A PLEA OF GUILTY OR NOLO CONTENDERE, INCLUDING THE MAXIMUM PENALTY AND ADMINISTRATIVE SANCTIONS AND THE POSSIBLE LEGAL EFFECTS AND MAXIMUM PENALTIES INCIDENT TO SUBSEQUENT CONVICTIONS FOR THE

SAME OR SIMILAR OFFENSES;
THE EFFECTS OF PROBATION;
IF YOU ARE NOT A CITIZEN, YOU ARE HEREBY ADVISED THAT A CONVICTION OF THE OFFENSE FOR WHICH YOU HAVE BEEN CHARGED WILL HAVE THE CONSEQUENCES OF DEPORTATION, EXCLUSION FROM ADMISSION TO THE UNITED STATES, OR DENIAL OF NATURALIZATION PURSUANT TO THE LAWS OF THE UNITED STATES.
COUNSEL FOR THE DEFENDANT JOINS IN THE WAIVERS AND CONCURS IN THE PLEA.
COURT FINDS THAT EACH SUCH WAIVER IS KNOWINGLY, UNDERSTANDINGLY, AND EXPLICITLY MADE;
THE DEFENDANT PERSONALLY WITHDRAWS PLEA OF NOT GUILTY TO COUNT 01 AND PLEADS NOLO CONTENDERE WITH THE APPROVAL OF THE COURT TO A VIOLATION OF SECTION 242 PC IN COUNT 01. THE COURT FINDS THE DEFENDANT GUILTY.
COUNT (01) : DISPOSITION: CONVICTED
COURT FINDS THAT THERE IS A FACTUAL BASIS FOR DEFENDANT'S PLEA, AND COURT ACCEPTS PLEA.
NEXT SCHEDULED EVENT:
SENTENCING
DEFENDANT WAIVES ARRAIGNMENT FOR JUDGMENT AND STATES THERE IS NO LEGAL CAUSE

WHY SENTENCE SHOULD NOT BE PRONOUNCED. THE COURT ORDERED THE FOLLOWING JUDGMENT:
AS TO COUNT (01):
IMPOSITION OF SENTENCE SUSPENDED
DEFENDANT PLACED ON SUMMARY PROBATION
FOR A PERIOD OF 024 MONTHS UNDER THE FOLLOWING TERMS AND CONDITIONS:
SERVE 007 DAYS IN LOS ANGELES COUNTY JAIL
LESS CREDIT FOR 7 DAYS
PLUS $20.00 COURT SECURITY ASSESSMENT (PURSUANT TO 1465.8(A)(1) P.C.)
$30.00 CRIMINAL CONVICTION ASSESSMENT (PURSUANT TO 70373 G.C.)
$116.47 987.8 P.C. - ATTORNEY FEES
$400.00 DOMESTIC VIOLENCE FUND(PURSUANT TO 1203.097 P.C.)
DEFENDANT TO PAY FINE TO THE COURT CLERK
DEFENDANT SHALL PAY A RESTITUTION FINE IN THE AMOUNT OF $100.00 TO THE COURT
BY 06/15/10
TOTAL DUE: $666.47
IN ADDITION:
-OBEY ALL LAWS AND ORDERS OF THE COURT.
-OBEY ALL RULES AND REGULATIONS OF THE PROBATION DEPARTMENT.
-NOT OWN, USE OR POSSESS ANY DANGEROUS OR DEADLY WEAPONS, INCLUDING ANY FIREARMS, KNIVES OR OTHER CONCEALABLE WEAPONS.

-DO NOT USE OR THREATEN TO USE FORCE OR VIOLENCE ON ANY PERSON. DO NOT ANNOY, HARASS OR MOLEST ANY PERSON OR WITNESS INVOLVED IN THIS CASE, ESPECIALLY BLANCA LARA.
MAKE RESTITUTION TO VICTIM PURSUANT TO 1202.4(F) IN AN AMOUNT TO BE DETERMINED AT A HEARING.
.
STAY 100 YARDS AWAY FROM AND HAVE NO CONTACT WITH BLANCA LARA.
.
DEFENDANT TO ENROLL AND COMPLETE 52 WEEK DOMESTIC VIOLENCE PROGRAM. SHOW PROOF OF ENROLLMENT ON 08/05/09 AND COMPLETION BY 08/05/10 IN ROOM 403.
.
RESTITUTION HEARING SET IN DEPT. 10 @ 8:30 AM.
.

CASE NO. 9CP00752 PAGE NO. 5
DEF NO. 01 DATE PRINTED 06/03/13

RELEASE #AK559900 ISSUED.
COUNT (01): DISPOSITION: CONVICTED
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
08/05/09 830 AM RESTITUTION HEARING DIST COMPTON COURTHOUSE DEPT 010
NEXT SCHEDULED EVENT:
08/05/09 900 AM PROOF OF ENROLLMENT DIST COMPTON COURTHOUSE DEPT 403
NEXT SCHEDULED EVENT:
08/05/10 900 AM PROOF OF DOMESTIC VIOL CLASS DIST COMPTON COURTHOUSE DEPT 403

CUSTODY STATUS: RELEASED ON OWN RECOGNIZANCE

ON 06/15/09 AT 900 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR PRETRIAL HEARING
PARTIES: PAT CONNOLLY (JUDGE) STACY RUCKER (CLERK)
KAREN DIX (REP) PAUL A. THOMPSON (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER
NEXT SCHEDULED EVENT:
06/15/10 830 AM PROOF OF FINE PAYMENT DIST COMPTON COURTHOUSE DEPT 403

ON 08/05/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR RESTITUTION HEARING
PARTIES: PAT CONNOLLY (JUDGE) STACY RUCKER (CLERK)
KAREN DIX (REP) EUGENE K.CHONG (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
09/04/09 830 AM RESTITUTION HEARING DIST COMPTON COURTHOUSE DEPT 010
NEXT SCHEDULED EVENT:
PROOF OF ENROLLMENT

ON 08/18/09 AT 800 AM :

THIS CASE IS REFERRED TO DEPT. 9 FOR FURTHER PROCEEDINGS.
DEFENDANT FAILED TO COMPLY WITH DOMESTIC VIOLENCE PROGRAM.

ON 09/04/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 010

CASE CALLED FOR RESTITUTION HEARING
PARTIES: PAT CONNOLLY (JUDGE) STACY RUCKER (CLERK)
KAREN DIX (REP) EUGENE K.CHONG (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER
BENCH WARRANT IS RECALLED AND QUASHED.
.
RESTITUTION HEARING IS OFF CALENDAR.
DEFENDANT IS ORDERED TO FILE PROOF OF ENROLLMENT ON 9/25/09.

CASE NO. 9CP00752 PAGE NO. 6
DEF NO. 01 DATE PRINTED 06/03/13

COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
09/25/09 830 AM PROOF OF ENROLLMENT DIST COMPTON COURTHOUSE DEPT 010

ON 09/08/09 AT 830 AM :

NEXT SCHEDULED EVENT:
09/25/09 830 AM PROOF OF ENROLLMENT DIST COMPTON COURTHOUSE DEPT 004

ON 09/25/09 AT 830 AM IN COMPTON COURTHOUSE DEPT 004

CASE CALLED FOR PROOF OF ENROLLMENT
PARTIES: DIANA SUMMERHAYES (JUDGE) ADOLFO RAMOS (CLERK)

CHRIS FOX (REP) TI-OSHA N. MURRAY (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY ALISON J. KLEIN DEPUTY PUBLIC DEFENDER
PROOF OF ENROLLMENT OF THE DOMESTIC VIOLENCE PROGRAM FILED IN COURT.
DEFENDANT GIVEN NEW COURT DATES FOR PROGRESS REPORT AND COMPLETION OF PROGRAM.
NEXT SCHEDULED EVENT:
03/25/10 830 AM PROGRESS REPORT DIST COMPTON COURTHOUSE DEPT 004
NEXT SCHEDULED EVENT:
10/22/10 830 AM PROOF OF DOMESTIC VIOL CLASS DIST COMPTON COURTHOUSE DEPT 403

ON 01/14/10 AT 830 AM :

DEFENDANT FAILED TO COMPLY WITH RULES AND REGULATIONS OF THE DOMESTIC VIOLENCE PROGRAM/CASE IS SENT TO DIV4 FOR REVIEW

ON 01/19/10 AT 830 AM :

PARTIES: MICHAEL SHULTZ (JUDGE) NONE (CLERK)
NONE (REP) NONE ()
DEFENDANT IS NOT PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PROBATION REVOKED
AS TO COUNT (01):
DEFENDANT FAILED TO: COMPLY WITH PROGRAM
.
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
BENCH/WARRANT ISSUED

01/19/10 BENCH WARRANT IN THE AMOUNT OF $30,000.00 BY ORDER OF JUDGE MICHAEL SHULTZ ISSUED. (01/27/10).

ON 03/25/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 005

CASE NO. 9CP00752 PAGE NO. 7
DEF NO. 01 DATE PRINTED 06/03/13

NUNC PRO TUNC ORDER PREPARED. IT APPEARING TO THE COURT THAT THE MINUTE ORDER IN THE ABOVE ENTITLED ACTION DOES NOT PROPERLY REFLECT THE COURT'S ORDER. SAID MINUTE ORDER IS AMENDED NUNC PRO TUNC AS OF THAT DATE. ALL OTHER ORDERS ARE TO REMAIN IN FULL FORCE AND EFFECT. DETAILS LISTED AT END OF THIS MINUTE ORDER.
CASE CALLED FOR BENCH WARRANT HEARING
PARTIES: ELLEN DESHAZER (JUDGE) JAN ULIBARRI (CLERK)
LYRRA LAMAR (REP) EUGENE K.CHONG (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY BRAD LEE MAHLER DEPUTY PUBLIC DEFENDER
PROBATION REINSTATED.
PROBATION IS CONTINUED ON THE SAME TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATIONS:
AS TO COUNT (01):
7 DOMESTIC VIOLENCE CLASSES CURRENTLY ENROLLED AT COMPTON ADULT SCHOOL
PROOF OF ENROLLMENT FILED WITH COURT
PROGRESS REPORT DUE 5-24-10 IN DEPT5
NUC PRO TUNC ORDERED PREPARED ON 3-29-10 BY (220739) SAID MINUTE

ORDER IS AMENDED AS FOLLOW: NEXT EVENT CODE SHOULD READ PROGRESS REPORT NOT PROOF OF ENROLLMENT.
(220739)
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
05/24/10 830 AM PROGRESS REPORT DIST COMPTON COURTHOUSE DEPT 005

03/25/10 BENCH WARRANT IN THE AMOUNT OF $30,000.00 RECALLED. (03/25/10).

ON 05/24/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 005

CASE CALLED FOR PROGRESS REPORT
PARTIES: KAREN ACKERSON-BRAZILLE (JUDGE) PAULETTE FAIN (CLERK)
CHARMAIN D. CAMPBELL (REP) SHARON L. RANSOM (DA)
THE DEFENDANT FAILS TO APPEAR, WITHOUT SUFFICIENT EXCUSE AND NOT REPRESENTED BY COUNSEL
PROBATION REVOKED
AS TO COUNT (01):
THE DEFENDANT FAILS TO APPEAR FOR PROGRESS HEARING.

.
.
.
BENCH WARRANT IS ORDERED ISSUED FORTHWITH IN THE AMOUNT OF $50,000.
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
BENCH/WARRANT TO ISSUE

05/24/10 BENCH WARRANT IN THE AMOUNT OF $50,000.00 BY ORDER OF JUDGE KAREN ACKERSON-BRAZILLE ISSUED. (05/24/10).

ON 05/25/10 AT 800 AM :

THIS MATTER IS SET FOR BENCH WARRANT HEARING IN DEPARTMENT #1

ON 05/25/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 001

CASE NO. 9CP00752 PAGE NO. 8
DEF NO. 01 DATE PRINTED 06/03/13

CASE CALLED FOR BENCH WARRANT HEARING
PARTIES: COMR. MICHAEL KAUTZ (JUDGE) RON DRABOS (CLERK)
BARBARA B. GIBBONS (REP) LORI L. GRAY (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY KATHLEEN RALEIGH DEPUTY PUBLIC DEFENDER
DEFENDANT AND COUNSEL ADMIT TO VIOLATION OF PROBATION IN OPEN COURT.
COURT FINDS DEFENDANT IN VIOLATION OF PROBATION.
PROBATION REINSTATED.
PROBATION IS CONTINUED ON THE SAME TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATIONS:
AS TO COUNT (01):
THE ABOVE FINE IS PAYABLE AT $50 PER MONTH ON THE 25TH DAY OF THE MONTH BEGINNING 06/25/10 AND CONTINUING UNTIL FULLY PAID.
PROGRESS REPORT FOR THE DOMESTIC VIOLENCE PROGRAM IS FILED
COMPLETION IS DUE BY 3-31-11 IN THE CLERK'S OFFICE.
:
DEFENDANT IS TO PAY ALL COURT FEE'S IN MONTHLY FINE PAYMENT'S

STARTING 6-25-10 IN ROOM 403:
DMV ABSTRACT NOT REQUIRED
CORRECTED AMENDED 05/25/10
NEXT SCHEDULED EVENT:
03/31/11 830 AM PROOF OF DOMESTIC VIOL CLASS DIST COMPTON COURTHOUSE DEPT 403
NEXT SCHEDULED EVENT:
06/25/10 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

05/25/10 BENCH WARRANT IN THE AMOUNT OF $50,000.00 RECALLED. (05/25/10).

CUSTODY STATUS: ON PROBATION

ON 06/29/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) NONE (DDA)
DEFENDANT IS PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PAYMENT IN THE AMOUNT OF $50.00 PAID ON 06/29/10 RECEIPT # COM474071007

NEXT SCHEDULED EVENT:
07/26/10 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

ON 07/26/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) NONE (DDA)
DEFENDANT IS PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PAYMENT IN THE AMOUNT OF $50.00 PAID ON 07/26/10 RECEIPT # COM415382002
NEXT SCHEDULED EVENT:
08/25/10 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

ON 09/03/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)

CASE NO. 9CP00752 PAGE NO. 9
DEF NO. 01 DATE PRINTED 06/03/13

NONE (REP) NONE (DDA)
DEFENDANT IS PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PAYMENT IN THE AMOUNT OF $50.00 PAID ON 09/03/10 RECEIPT # COM533293020
UPDATED BY: 512160
NEXT SCHEDULED EVENT:
09/27/10 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

ON 09/20/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) NONE (DDA)
DEFENDANT IS PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PAYMENT IN THE AMOUNT OF $50.00 PAID ON 09/20/10 RECEIPT # COM442722025
UPDATED BY: 512160
NEXT SCHEDULED EVENT:

11/22/10 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

ON 09/21/10 AT 800 AM :

THIS MATTER IS SET FOR FURTHER PROCEEDINGS IN DEPARTMENT #1
NEXT SCHEDULED EVENT:
09/21/10 830 AM FURTHER PROCEEDINGS DIST COMPTON COURTHOUSE DEPT 001

ON 09/21/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 001

CASE CALLED FOR FURTHER PROCEEDINGS
PARTIES: COMR. MICHAEL KAUTZ (JUDGE) RON DRABOS (CLERK)
BARBARA B. GIBBONS (REP) LORI L. GRAY (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY KATHLEEN RALEIGH DEPUTY
PUBLIC DEFENDER
PROGRESS REPORT RE: 52 WEEK DOMESTIC VIOLENCE BATTERERS' PROGRAM
IS FILED WITH THE COURT INFORMING THE COURT THAT THE DEFENDANT

HAS ATTENDED 15 SESSIONS.
.
THE COURT PERMITS THE DEFENDANT TO ATTEND THE REMAINING 52 WEEK
DOMESTIC VIOLENCE BATTERERS' PROGRAM SESSIONS IN FRESNO.
.
ON MOTION OF THE COURT, MATTER IS CONTINUED FOR PROOF OF
COMPLETION OF THE 52 WEEK DOMESTIC VIOLENCE BATTERERS' PROGRAM
ON 7/29/11 AT 8:30 A.M. IN DEPARTMENT 5.
.
THE DEFENDANT IS ORDERED TO REPORT TO ROOM 403 FORTHWITH TO
ENTER INTO A PAYMENT INSTALLMENT CONTRACT.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
09/21/10 900 AM CONTRACT PAYMENTS DIST COMPTON COURTHOUSE DEPT 403

CASE NO. 9CP00752 PAGE NO. 10
DEF NO. 01 DATE PRINTED 06/03/13

NEXT SCHEDULED EVENT:
07/29/11 830 AM PROOF OF DOMESTIC VIOL CLASS DIST COMPTON COURTHOUSE
DEPT 005

CUSTODY STATUS: ON PROBATION

ON 11/22/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) NONE (DDA)
DEFENDANT IS NOT PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
DEFENDANT HAS UNTIL 7-29-11 TO PAY RESTITUTION IN FULL IN ROOM
403.
NEXT SCHEDULED EVENT:
07/29/11 900 AM RESTITUTION PAYMENT DIST COMPTON COURTHOUSE DEPT 403

ON 12/21/10 AT 830 AM IN COMPTON COURTHOUSE DEPT 005

CASE CALLED FOR JUDICIAL ACTION
PARTIES: KAREN ACKERSON-BRAZILLE (JUDGE) JOYCE KAMIDA (CLERK)
NONE (REP) NONE (DA)
DEFENDANT IS NOT PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PROBATION REVOKED
AS TO COUNT (01):
DEFENDANT FAILED TO COMPLY WITH RULES OF THE DOMESTIC VIOLENCE
BATTERERS' PROGRAM. BENCH WARRANT IS ORDERED ISSUED. BAIL IS
SET IN THE AMOUNT OF $26,000.
.
*MINUTES ARE ENTERED ON 12-27-10 BY J. KAMIDA PER THE WRITTEN
ORDER OF JUDGE ACKERSON/BRAZILLE SIGNED ON 12-23-10 CONTAINED IN
THE CASE FILE.
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
PROBATION REVOKED/BW ISSUED

ON 12/21/10 AT 830 AM :

DEFENDANT FAILED TO COMPLY WITH RULES AND REGULATIONS OF THE
DOMESTIC VIOLENCE PROGRAM/CASE IS SENT TO DIV5 FOR REVIEW

12/27/10 BENCH WARRANT IN THE AMOUNT OF $26,000.00 BY ORDER OF JUDGE KAREN
ACKERSON-BRAZILLE ISSUED. (12/27/10).

ON 02/04/11 AT 130 PM IN COMPTON COURTHOUSE DEPT 009

CASE CALLED FOR BENCH WARRANT HEARING
PARTIES: LYNN D. OLSON (JUDGE) CARLA CRANE (CLERK)
ROSE M. SAUCEDO (REP) CRAIG ROUVIERE (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY D BRIAN WOO DEPUTY PUBLIC
DEFENDER
DEFENDANT AND COUNSEL ADMIT TO VIOLATION OF PROBATION IN OPEN COURT.
COURT FINDS DEFENDANT IN VIOLATION OF PROBATION.

PROBATION REINSTATED.
PROBATION MODIFIED AS FOLLOWS:
AS TO COUNT (01):
THE COURT ORDERS DEFENDANT TO PERFORM 10 AA CLASSES WITH PROOF OF COMPLETION DUE ON 3/4/11.
.
DV CLASSES MAY BE COMPLETED OUT OF COUNTY.
.
PAYMENT PLAN IS VACATED AND PAYMENT DUE IN FULL ON 8/4/11.
DMV ABSTRACT NOT REQUIRED
NEXT SCHEDULED EVENT:
03/04/11 830 AM PROOF OF ENROLLMENT DIST COMPTON COURTHOUSE DEPT 009
NEXT SCHEDULED EVENT:
08/04/11 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

02/04/11 BENCH WARRANT IN THE AMOUNT OF $26,000.00 RECALLED. (02/04/11).

CUSTODY STATUS: ON PROBATION

ON 03/04/11 AT 830 AM IN COMPTON COURTHOUSE DEPT 009

CASE CALLED FOR PROOF OF ENROLLMENT
PARTIES: LYNN D. OLSON (JUDGE) BEVERLY WARD (CLERK)
SUSAN ELLIS (REP) MARIA ANDREA DAVALOS (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY D BRIAN WOO DEPUTY PUBLIC DEFENDER
PROOF OF ENROLLMENT IN DOMESTIC VIOLENCE PROGRAM FILED.
PROOF OF COMPLETION OF 10 AA MEETINGS FILED.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
06/03/11 830 AM PROGRESS REPORT DIST COMPTON COURTHOUSE DEPT 009

CUSTODY STATUS: RELEASED ON OWN RECOGNIZANCE

ON 04/06/11 AT 830 AM IN COMPTON COURTHOUSE DEPT 009

CASE CALLED FOR MODIFICATION OF PROBATION
PARTIES: LYNN D. OLSON (JUDGE) BEVERLY WARD (CLERK)
SUSAN ELLIS (REP) CRAIG ROUVIERE (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY ERIK A. RODSTROM DEPUTY PUBLIC DEFENDER
DEFENDANT RESIDES BACK IN LOS ANGELES COUNTY. CLASSES TO RESUME IN LOS ANGELES COUNTY.
.
**********6/3/11 PROGRESS REPORT DATE TO REMAIN **********
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
PROGRESS REPORT

CUSTODY STATUS: RELEASED ON OWN RECOGNIZANCE

ON 04/18/11 AT 830 AM :

CASE NO. 9CP00752 PAGE NO. 12
DEF NO. 01 DATE PRINTED 06/03/13

PROOF OF ENROLLMENT IS RECEIVED AND FILED THIS DATE.
.
THE MATTER REMAINS AS PREVIOUSLY SET FOR HEARING ON 06/03/11 IN
THIS DEPARTMENT.

ON 06/03/11 AT 830 AM IN COMPTON COURTHOUSE DEPT 009

CASE CALLED FOR PROGRESS REPORT
PARTIES: LYNN D. OLSON (JUDGE) BEVERLY WARD (CLERK)
SUSAN ELLIS (REP) CRAIG ROUVIERE (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY JAMES NEPTUNE DEPUTY PUBLIC
DEFENDER
PROGRESS REPORT FILED. TOTAL 41 OUT OF 52 CLASSES COMPLETED.
.
PROOF OF COMPLETION OF DOMESTIC VIOLENCE CLASSES 9/9/11 DEPT.9

11 CLASSES NEEDED FOR COMPLETION.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
09/09/11 830 AM PROOF OF DOMESTIC VIOL CLASS DIST COMPTON COURTHOUSE
DEPT 009
NEXT SCHEDULED EVENT:
12/05/11 830 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

ON 09/09/11 AT 830 AM IN COMPTON COURTHOUSE DEPT 009

CASE CALLED FOR PROOF OF DOMESTIC VIOL CLASS
PARTIES: LYNN D. OLSON (JUDGE) BEVERLY WARD (CLERK)
ALEX LEE (REP) BRANDY CHASE (DA)
DEFENDANT IS PRESENT IN COURT, AND REPRESENTED BY JAMES NEPTUNE DEPUTY PUBLIC
DEFENDER
PROOF OF COMPLETION OF DOMESTIC VIOLENCECLASSES FILED.
.
DEFENSE REQUEST TO TERMINATE PROBATION IS HEARD AND DENIED

WITHOUT PREJUDICE.
COURT ORDERS AND FINDINGS:
-THE COURT ORDERS THE DEFENDANT TO APPEAR ON THE NEXT COURT DATE.
NEXT SCHEDULED EVENT:
FINES/FEES

ON 12/05/11 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) BRANDY CHASE ()
DEFENDANT IS NOT PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
DEFENDANT GRANTED 60 DAY EXTENSION FOR FINE AND FEES UNTIL
2-6-12
NEXT SCHEDULED EVENT:
02/06/12 900 AM FINES/FEES DIST COMPTON COURTHOUSE DEPT 403

CASE NO. 9CP00752
DEF NO. 01

ON 02/06/12 AT 830 AM IN COMPTON COURTHOUSE DEPT 403

CASE CALLED FOR FINES/FEES
PARTIES: NONE (JUDGE) NONE (CLERK)
NONE (REP) NONE (DDA)
DEFENDANT IS PRESENT IN COURT, AND NOT REPRESENTED BY COUNSEL
PAYMENT IN THE AMOUNT OF $466.47 PAID ON 02/06/12 RECEIPT # COM256829013
UPDATED BY: 459047
NEXT SCHEDULED EVENT:
PROCEEDINGS TERMINATED

05/03/13 ARREST DISPOSITION REPORT SENT VIA FILE TRANSFER TO DEPARTMENT OF JUSTICE

CLERK OF IOWA DISTRICT COURT

CLERK'S CERTIFICATE

05771 SRCR327439
EXPUNGED

IN THE IOWA DISTRICT COURT, POLK COUNTY,

I, Anne M. Sheeley, Clerk of Iowa District Court in and for Polk County, the same being a Court of Record, having a Seal, and having exercising general original jurisdiction in court proceedings, do hereby certify that I am the proper custodian of all the books, papers, records, files and documents of or appertaining to said Court, and of the Seal thereof.

I further certify that I have carefully compared the annexed copy of:

Complaint / Sentencing

with the original record and files of this office. and that the same is a true and correct copy therefrom, and the whole of such original records and papers.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seal of said Court, at Des Moines, in said County and State. this 5th day of May, 2020.

Anne M. Sheeley

POLK COUNTY CLERK OF COURT

/s/ Wes Dowell

Designee

E-FILED 2019 MAY 17 10:36 AM POLK - CLERK OF DISTRICT COURT

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA, *Plaintiff,* v. LIZABETH LARA, *Defendant.*	CRIMINAL NO:SRCR327439 SENTENCING ORDER (SERIOUS MISDEMEANOR) ☑ Defendant in custody.

Defendant appears in person and with counsel, ***D. Page***, on charge of ***POSSESSION OF CONTROLLED SUBSTANCE 1ST OFFENSE*** in violation of Iowa Code Section(s) ***124.401(5)***. The State was represented by ***James Hathaway for Leslie Nesbit***.

☐ Defendant also appears with interpreter: _____.

☐ Defendant previously waived his/her right to an attorney.

☑ Defendant waived reporting and record of the Sentencing Hearing.

☑ Defendant **PLEADS GUILTY** to the offense set out above. The Court has reviewed the signed petition to plead guilty and considered the statements of the Defendant. The Court finds the Defendant understands the charge, the penal consequences and the constitutional rights being waived. Based on the statements of the Defendant, statements of the prosecutor, and the minutes of testimony accepted as true by the Defendant and considered by the Court, the plea has a factual basis and is knowingly, voluntarily and intelligently made. **DEFENDANTS PLEA IS ACCEPTED.**

☐ Defendant **PLEADS GUILTY** to the offense set out above pursuant to North Carolina v. Alford, 400 U.S. 25 (1970). The Court has reviewed the signed petition to plead guilty and considered the statements of the Defendant. The Court finds the Defendant understands the charge, the penal consequences and the constitutional rights being waived. The Court further **FINDS** that the Defendant has concluded that his/her interests require entry of a guilty plea and Defendant received a substantial benefit in return for the entry of the guilty plea. The Defendant has nothing to gain by a trial and much to gain by entry of the plea. By reviewing the Trial Information, Minutes of testimony, police reports and considering statements of Counsel, the Court **FINDS** that there is strong evidence of Defendant's guilt which substantially negates Defendant's claim of innocence. **DEFENDANT'S PLEA IS ACCEPTED.**

☑ Defendant **SEEKS IMMEDIATE SENTENCING** and waives time before sentencing and a presentence investigation report.

☐ Defendant **APPEARS FOR SENTENCING** having previously pled guilty to the offense set out above.

☐ Defendant was found guilty ☐ following a trial to the Court ☐ by a trial jury.

☐ A presentence investigation report has been completed and reviewed by the Court, the Defendant, Defense counsel and the County Attorney. Any exceptions and/or corrections were set forth on the record or on the face of the presentence investigation report.

On inquiry, no legal cause has been shown to prevent sentencing on this date. Defendant was given an opportunity to speak in mitigation of the sentence. The following sentence is based on all of the available **SENTENCING CONSIDERATIONS** set out in Iowa Code section 907.5. The court finds the following factors the most significant in determining this particular sentence:

☑ The nature and circumstances of the crime	☐ Statutory sentence requirements	☐ Victim impact statement
☐ Protection of the public from further offenses	☐ Defendant's statement	☑ Defendant's age and character
☐ Defendant's criminal history	☐ Defendant's mental health history	☑ Defendant's employment
☐ Defendant's substance abuse history	☐ Defendant's family circumstances	☑ The Plea Agreement
☑ Defendant's propensity for further criminal acts	☑ Maximum opportunity for rehabilitation	☐ _____

☑ **JUDGMENT IS DEFERRED.** The Court Orders the Clerk of Court to expunge Defendant's record in this matter and any other related dismissed charges resulting in the deferred judgment upon successful completion of all terms of probation and discharge from probation and when all financial obligations are paid in full. Defendant shall pay a $315 civil penalty, law enforcement initiative surcharge (if applicable) and drug surcharge (if applicable) which is due immediately and is considered delinquent after 30 days.

☐ **DEFENDANT IS ADJUDGED GUILTY** of the above charge in violation of the above stated code section(s). **Defendant is fined $315 plus surcharge**, which, in addition to any other surcharges imposed, is due immediately and is considered delinquent 30 days after due date. ☐ Fine is suspended due to Defendant's incarceration.

E-FILED 2019 MAY 17 10:36 AM POLK - CLERK OF DISTRICT COURT

☐ Defendant shall be **INCARCERATED FOR ONE YEAR.** This sentence is suspended except for _____ days. Credit Defendant with all days served.

☐ Defendant shall be incarcerated for _____ days. ☐ Credit Defendant with _____ days served.

☐ Defendant shall serve from _____ at _____ ☐ am ☐ pm to _____ at _____ ☐ am ☐ pm in jail.

☐ Probation is denied based on the sentencing considerations set out above.

☑ Defendant is placed on probation beginning from the date of this order, or, if a term of incarceration is imposed, immediately upon defendant's release from custody, for a period of one year to be supervised by the Department of Correctional Services (DCS). The length of probation is based on the sentencing considerations set out above. The level of supervision shall be determined by DCS. Defendant is to comply with all term of probation as set forth herein and any terms imposed by DCS as required by the Intermediate Criminal Sanctions Program. Defendant is ordered to obey all federal, state or city laws or ordinances while on probation. Defendant is to notify his/her probation supervisor immediately upon any arrest or change of address. Defendant shall pay any probation administration fees. A violation of this paragraph or this order is a violation of probation. This probation is subject to revocation by the Court under Iowa Code Chapter 908, on notice and an opportunity for hearing and a finding that the Defendant has failed to fairly live within the terms of probation and the law. Such a finding may result in revocation of probation and incarceration or a finding of Contempt of Court under Iowa Code Section 665.4 for which Defendant could receive up to six months in jail, a $500 fine, or both.

☐ Defendant is ordered to report to the probation office on the 1st floor of the Criminal Courts Building immediately following sentencing to enter into a probation agreement. If the probation office is closed, Defendant shall report to the probation office on the 1st floor of the Criminal Courts Building by 10:00 a.m. of the next business day.

☑ Defendant is ordered to report to the probation office on the 1st floor of the Criminal Courts Building between 8:00 a.m. and 10:00 a.m. on the first business day after released from incarceration to enter into a probation agreement.

☐ **D.A.R.E SURCHARGE.** Pursuant to Iowa Code section 911.2 the defendant is assessed a D.A.R.E. surcharge ($10) for each above-listed violation of Iowa Code Chapter 321J or 124 division IV. However, this surcharge is not assessed for any offense for which the court deferred sentence or judgment, or suspended the sentence.

☑ **LAW ENFORCEMENT INITIATIVE SURCHARGE.** Pursuant to Iowa Code section 911.3, the defendant is assessed a law enforcement initiative surcharge ($125) for each above-listed violation of Iowa Code Chapter 124, 155A, 453B, 713, 714, 715A, or 716, or section 719.7, 719.8, 725.1, 725.2 or 725.3.

☐ **DOMESTIC ABUSE ASSAULT, SEXUAL ABUSE, STALKING, AND HUMAN TRAFFICKING VICTIM SURCHARGE.** Pursuant to Iowa Code section 911.2B, the defendant is assessed a domestic abuse assault, sexual abuse, stalking, and human trafficking victim surcharge ($100) for each above-listed violation of Iowa Code Chapter 709, or section 708.2A, 708.11 or 710A.2.

☑ Defendant has received a substance abuse evaluation within 3 business days. If a recommendation was received, Defendant shall pay for, cooperate with and complete the recommended programming. Defendant shall begin programming within 30 days of this order. Defendant shall file proof of compliance and completion with his/her probation officer.

☑ Defendant shall be placed on color code (substance abuse monitoring by urine analysis (U.A.) during the term of probation. Defendant shall cooperate with this program in all respects.

☐ Defendant is ordered to make restitution in the amount of $ __. Payment(s) shall be made to the Clerk of Criminal Court, Polk County Criminal Courts Building, 110 Sixth Avenue, Des Moines, IA 50309. The Clerk shall forward payment(s) to _____. "TBD" indicates "to be determined" which means that the final, accurate restitution amounts are not available. When such amounts of restitution are available, the State may file an application for restitution and a supplemental restitution order may follow. Defendant has 30 days to contest the amount of restitution. ***DEFENDANT SHALL NOT BE DISCHARGED FROM PROBATION UNTIL ANY RESTITUTION DUE IS PAID IN FULL.***

☐ Defendant is ordered to participate in, cooperate with and complete a VORP session with each victim who so desires, including the victims of any dismissed charges, to discuss the crime, restitution amounts, and/or to establish a restitution payment plan. If victim restitution amounts are not determined/ resolved in the VORP, the State may file an application for restitution and a supplemental restitution order may follow. Defendant is ordered to call 286-3057 within three working days of this Order or release from jail to register for the VORP. Any No-Contact Order currently in effect shall be temporarily suspended for the VORP session. No-Contact Order shall be in full force and effect upon conclusion of VORP session.

E-FILED 2019 MAY 17 10:36 AM POLK - CLERK OF DISTRICT COURT

☐ Defendant is ordered to comply with the No Contact Order entered herein.

☐ Defendant is ordered to contact Des Moines Area Community College at 964-6800, (8:00 am to 4:00 pm Mon - Fri) or at ce.dmacctraining.com within three working days of this Order or release from jail to enroll in the program checked below. Defendant shall pay the class fee at the time of registration and complete class within 90 days. There is no same day registration.

☐ **FIRST-TIME OFFENDER** Class
☐ **REPEAT OFFENDER** Class
☐ **DRINKING DRIVER'S** Class
☐ **ASSAULTIVE BEHAVIOR** Class
☐ **LICENSE UNDER SUSPENSION** Class
☐ **DRIVER IMPROVEMENT** Class

☑ Defendant is ordered to complete ***50*** hours of community service within ***90*** days of the date of this order. Defendant shall sign up for community service at the time of entering into the probation agreement.

☐ The Sentence entered herein is ☐ Consecutive ☐ Concurrent to the sentence imposed in _____.

☑ Pursuant to the plea agreement and upon the recommendation of the State, the following counts/cases are dismissed: ***SMAC381801***. Pursuant to the plea agreement Defendant is ordered to pay court costs on these counts/cases and if restitution is due on any of these counts/cases, Defendant is ordered to pay such restitution. Iowa Code Section 901C.1 allows a defendant to file a motion to request that a dismissed case be expunged from the Clerk of Court's public records. Before the expungement may be granted, all of the following must be true:

1) All charges in the case are dismissed.
2) At least 180 days have passed since the case was dismissed or the defendant proves, and the court finds, good cause to expunge the records sooner.
3) The dismissal was not based on a finding that the defendant was incompetent to stand trial nor was the defendant found not guilty by reason of insanity.
4) All court costs, fees, or other financial obligations ordered by the court have been paid.

☐ Case Number(s) _____ being dismissed by this order are related cases to the charge for which Defendant is receiving a deferred judgment.

☐ **RECALL WARRANT**

☐ _____

Pursuant to Iowa Code Section 815.9(5), if the Defendant is receiving court appointed legal assistance, the Court finds upon inquiry, review of the case file and any other information provided by the parties, the Defendant has the reasonable ability to pay restitution of fees and costs in the amount approved by the State Public Defender x☐or $ ***0*** whichever is less. Defendant does not have the reasonable ability to pay attorney fees.

Defendant is ordered to immediately pay any and all restitution, fines, surcharges, and court costs. All payments shall be made to Clerk of Court, Polk County Criminal Courts Building, 110 6th Avenue, Des Moines, Iowa 50309 or on line at www.iowacourts.gov. Defendant shall call the Clerk of Court at 286-3760 to verify all amounts owed. ***These amounts are considered delinquent 30 days after their due date.*** NOTICE: If the Defendant fails to pay the total financial obligation due the case will be transferred for collection. The State of Iowa may withhold any State income tax refund, vehicle registration and/or driver's license issuance for unpaid court ordered financial obligations.

If judgment was not deferred, Defendant has a ***right to appeal*** this judgment to the Iowa Supreme Court. To perfect an appeal, Defendant must file a written Notice of Appeal with the Clerk of Court no later than 30 days from the date of this Order. If Defendant fails to file the Notice of Appeal, Defendant waives and gives up his/her right to appeal this judgment. A copy of Defendant's Notice of Appeal must be delivered to the Iowa Attorney General with proof of service. If Defendant cannot afford an attorney or the cost of an appeal and qualifies for court appointed counsel, an attorney and necessary documents will be furnished at State expense.

Bond on appeal is set at $***1,000*** Cash Only. Court costs are taxed to the Defendant.

Mittimus on any remaining jail days shall issue immediately.

E-FILED 2019 MAY 17 10:36 AM POLK - CLERK OF DISTRICT COURT

☑ Defendant was personally served with a copy of this order.
☐ _____ was personally served with a copy of this order.
☐ In addition to all other persons entitled to a copy of this order, the Clerk shall provide a copy to the following: DAJCC, _____

E-FILED 2019 MAY 17 10:36 AM POLK - CLERK OF DISTRICT COURT

State of Iowa Courts

Case Number SRCR327439
Case Title STATE VS LIZABETH LARA
Type: ORDER OF DISPOSITION

So Ordered

Becky Goettsch, District Associate Judge,
Fifth Judicial District of Iowa

Electronically signed on 2019-05-17 10:36:24

E-FILED 2019 MAY 8 7:08 AM POLK - CLERK OF DISTRICT COURT

In the Iowa District Court for Polk County

State of Iowa, *Plaintiff,* v. **Lizabeth Lara,** *Defendant.*	**Agency Case No.: DM19-13530** **Agency: Des Moines Police Department** **County Attorney** **Preliminary Complaint Review**

COMES NOW the undersigned Assistant Polk County Attorney and states as follows:

I have read and reviewed the attached complaint and affidavit. I:

[X] *Approve* the charge as POSSESSION OF CONTROLLED SUBSTANCE 1ST OFFENSE—Serious Misdemeanor—in violation of Iowa Code Section 124.401(5) and ask the court to find probable cause for this charge.
[ ] Request that the Court enter the attached ***Arrest Warrant.***
[ ] Advise the court and the clerk of court that despite the officer's request for an Arrest Warrant, the defendant has reportedly been taken into custody, so ***an arrest warrant is no longer required.***

With regard to a bond amount, the State requests that:

[ ] The State requests that the Court enter the attached ***No Contact Order.***
[ ] The State requests defendant be held without bond until initial appearance, so a ***No Contact Order*** may be entered with the following victim at the following location:
_____.
[X] Bond be set according to the uniform bond schedule at Initial Appearance.

WHEREFORE the State respectfully requests the Court find probable cause and allow the case to proceed under the circumstances set out above.

Respectfully submitted,
JOHN P. SARCONE by:

/s/ Linda Zanders
Assistant Polk County Attorney
Polk County Attorney's Office
222 Fifth Avenue, Des Moines, IA
(515) 286-3737
ctyatty@polkcountyiowa.gov

E-FILED 2019 NOV 26 11:07 AM POLK - CLERK OF DISTRICT COURT

IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

STATE OF IOWA, Plaintiff VS **Lizbeth Lara,** Defendant	Criminal Number(s): SRCR327439 **PROBATION DISCHARGE ORDER**

IT IS THEREFORE ORDERED that for the reason(s) set forth below the defendant is hereby discharged from probation.

☒ All requirements of probation have been satisfied/addressed.

☒ It is the further order of the Court, the defendant having been granted a deferred judgment under section 907.3, that the Court's criminal records with reference to the deferred judgment shall be expunged only when all court ordered financial obligations are satisfied.

☐ It is the further order of the Court, that the defendant has reached the maximum permissible term of probation and the defendant has outstanding court ordered financial obligations and is unable (due to incarceration) or is not eligible to enter into a payment plan. The Clerk of Court shall immediately submit this case to the County Attorney, Department of Revenue and/or the County Treasurer for collection.

For information regarding his/her right to vote and hold public office in Iowa and restoration of firearms rights and a pardon, please refer to the following link: https://governor.iowa.gov/constituent-services/restoration-of-citizenship-rights/. **(Felony & Aggravated Misdemeanor Convictions ONLY).**

☒ **Clerk shall mail a copy of this order to the defendant. 938 E. 90th Street, Los Angeles, CA 90002**

☒ In addition to all other persons entitled to a copy of this order, the clerk shall provide a copy to the following:

DCS-PO Kirts

E-FILED 2019 NOV 26 11:07 AM POLK - CLERK OF DISTRICT COURT

State of Iowa Courts

Type: ORDER OF DISCHARGE

Case Number	**Case Title**
SRCR327439	STATE VS LIZABETH LARA

So Ordered

Tabitha Turner, District Associate Judge,
Fifth Judicial District of Iowa

E-FILED 2019 MAY 8 7:08 AM POLK - CLERK OF DISTRICT COURT

IN THE IOWA DISTRICT COURT IN AND FOR
POLK COUNTY

This Complaint and Affidavit is to be:

- ☐ Filed with Court Clerk (cc: CA)
- ☒ Submitted to County Attorney
- ☐ Filed with JCO - Defendant is a Juvenile

Agency Case Number: 20190013530
Arrest Date: 05/08/2019

THE STATE OF IOWA

VS

OFFENDER

Last	First	Middle	Suffix	
LARA	LIZABETH			
Address	**City**		**State**	**Zip Code**
[redacted] SOUTH UNION ST	DES MOINES		IA	50315

DL #	State	DL Class	DL Endorsements	DL Restrictions
[redacted]	IA	C		

Date of Birth	Gender	Race	Ethnicity
[redacted]	FEMALE	WHITE - W	HISPANIC ORIGIN - H

Height	Weight	Eye Color	Hair Color
5' 02"	150 LBS		BLACK - BLK

OFFENSE

State	County	Local	Code Section	Crime Description	Speed	In Zone
☒	☐	☐	124.401(5)	POSSESSION OF CONTROLLED SUBSTANCE 1ST OFFENSE		

Class	Serious P.I.	Fatal Accident	Civil Damage Assessment	Other
SRMS	☐	☐	☐	☐

Location Type: 20 - RESIDENCE/HOME

Literal Description: 1504 11TH ST.

Address	City	State	Zip Code
1504 11TH ST.	DES MOINES	IA	50314

Is Date and Time of Incident Known?	Incident Date or Low Range	Upper Date Range	Incident Time or Low Range	Upper Time Range
YES	05/08/2019		00:30	

STATUS OF OFFENDER/JUVENILE

☒ TAKEN INTO CUSTODY	CUSTODY: 1 - JAILED	☐ SUMMONS TO APPEAR (Citation Issued)
☐ WARRANT REQUESTED	☐ NO CONTACT ORDER REQUESTED	☐ RELEASED TO PARENT/GUARDIAN

NARRATIVE

Narrative of Offense Committed

On or about the above stated date and time the Defendant did

knowingly or intentionally possess a controlled substance, to-wit: Methamphetamine, A Schedule II Controlled Substance

AFFIDAVIT

STATE OF IOWA, **POLK COUNTY**

I, the undersigned, being duly sworn, state that all facts contained in this Complaint and Affidavit known by me or told to me by other reliable persons form the basis for my belief that the defendant committed this crime

State all facts and persons relied upon supporting elements of alleged crime

On 8 May at around 00:30 the defendant was searched before being placed in a patrol car. While searching officers found a small baggie of a white crystal substance in the defendants front right pocket. The substance was filed tested and tested positive for methamphetamine.

Jordan Ulin ULIN, JORDAN 5244

Signature of Complainant or Officer, Officer Name & Number

E-FILED 2019 MAY 8 7:08 AM POLK - CLERK OF DISTRICT COURT

GENERAL PROBABLE CAUSE

Defendant Implicated
01 - POSSESSED DRUGS/PARAPHERNALIA, 02 - CAUGHT IN ACT, 08 - CRIME OBSERVED BY OFFICERS, 09 - NEAR SCENE OF CRIME, 11 - POSSESSION, 14 - OTHER PHYSICAL EVIDENCE

Operating Motor Vehicle in County	Other Physical Evidence	Attempted To Inflict Injury
	BODY WORN CAMERA	

POSSESSION

Possession of a Controlled Substance
1 - POSSESSED DRUGS, 2 - OBSERVED BY OFFICERS

Schedule Drugs
06 - METHAMPHETAMINE

Other Drugs

STATE OF IOWA, POLK COUNTY

NOTARIAL SEAL IOWA

Subscribed and sworn to before me by the person(s) signing the Complaint and Affidavit(s) on 05/08/2019

Notary Name **BENJAMIN MCCARTHY**

Commission Number **816594**

My Commission Expires **04/23/2022**

Signature of Verifying Party

☐ Peace Officer ☒ Notary ☐ Prosecuting Attorney

SINCE 1914

step into the light

The Midnight Mission

July 30, 2019

Board of Directors

Chairman
R. Stephen Doan, Esq.

Vice Chairman
Ali Razi

President & CEO
G. Michael Arnold

Secretary
David R. Doan

Directors
Larry Adamson
Saul Alvarado
Maria Beckman
Katherine Chrisman
Ronald Koretz, M. D.
Mark Liberman
William Noonan
Kristina "Tina" Olson
Ronald Robinson
Mark S. Rothstein
Michael Thom
Steve Watson
Jeremy Zhu

Managing Director
Clancy Imislund

Director Emeritus
H. Herbert Wilkins

To Whom It May Concern:

This letter is to confirm that Liz Lara has completed 53.5 hours of community service on July 29, 2019 by helping in our dining hall preparing and serving meals.

Founded in 1914, The Midnight Mission offers paths to self-sufficiency to men, women and children who have lost direction. Our emergency services and 12-step recovery, family living, job training, education and workforce development programs offer a compassionate bridge to achieve and maintain healthy, productive lives. We remove obstacles and provide the accountability and structure that people who are experiencing homelessness need to be productive in their communities. Our conviction and commitment to their success define us.

Thank you for serving at The Midnight Mission. Your time was essential to making a difference in the lives of those we serve.

Best Regards,

Andrew Linares
Community Events Coordinator

CHARITY NAVIGATOR
Four Star Charity

6235261

Date: 5/20/19

ACS
Avery Comprehensive Services Inc.
309 Court Ave, Suite 218
Des Moines, IA 50309
515-875-4880

To: KASEY KIRTZ PROBATION OFFICER

Client Name: LIZBETH LARA DOB; [redacted] SOCIAL; [redacted]
SRCR327439

Assessment Information

The client is a 29-year-old female, who is currently moved out of state to California recently; she reports her significant other is still rapping up loose ends like selling the house;
The client did not indicate experiencing any substance-related withdrawal symptoms. she stated that she is physically healthy and is not taking medications. She claims she used Meth one time; she has been using alcohol on the weekends; she denies smoking Marijuana for the last few years;
The client reported being emotional and embarrassed about the charge pending; the client was pleasant and cooperative during the evaluation, and she recognized her use has affected her life in legal aspects; Based upon the client's reported pattern and history of use, the client believes she has learned her lesson; He reported having a supportive recovery environment; she reports she is moving back home with the family; getting in to trouble was a huge mistake;

She reports she was trying to score Marijuana however she couldn't find any, so she got a little Meth;
The client has worked as a pharmacy Tec; she needs her deferred judgment; this writer believes the client does have personal issues;

Measurements

The results of the Simple Screening Instrument for Substance Abuse (SSI-SA) indicate the client's degree of risk for substance abuse is minimal; the results of the Lie-Bet Screening Instrument for Pathological Gambling indicated no referral for additional services necessary. The client responses to the Mental Health Screening Form III (MHSF-III) raise no possibility of a current problem with mental health issues;

Client Focus of Change

The client reported she is focused on making better responsible decisions in her life;

Level of Care Recommended (ASAM PPC-2R)

Based upon information obtained from the client; she reports she is leaving today; she reports she has been sentenced to probation and has seen her PO; SHE HAS BEEN PLACED ON COLOR CODE; SHOULD THE CLIENT HAS A POSETIVE UA SHE WILL ATTEND SUBSTANCE ABUSE TREATMENT; ANY QUESTIONS PLEASE LET ME KNOW;
The referral to THERAPY sessions is not mandatory, however this writer believes she would benefit by addressing past and present issues;

Gabi Twohey CADC
Substance Abuse Assessment Counselor
Avery Comprehensive Services
(515) 875-4860

7B

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

PHARMACEUTICAL TECHNICIAN APPLICATION Registration Fee: $50.00

(Non-refundable check or credit card only. Credit Cards are charged a 5% processing fee)

Complete Name (no abbreviations):

First: ANTONIO Middle: _____ Last: MADRID

Home Address: [redacted] RUBY AVENUE Apt#: _____

City: REDLANDS State: CA Zip Code: 92374

Telephone [redacted] SS# or ITIN: [redacted]

Date of Birth: [redacted] Place of Birth: LOS ANGELES Sex: X M or F

E-mail Address: [redacted]

To qualify as a pharmaceutical technician you will need to meet one of the following criteria. Please check the appropriate box and include the required documentation.

- X Copy of registration or on-line verification from state in which you are currently registered as a pharmaceutical technician.
- ☐ Copy of a certificate from an ASHP approved pharmacy technician school.
- ☐ Non ASHP approved school and PTCB or ICPT.

A licensee is not personally required to have a Nevada State Business License, however, if you have one, please provide the number: N/A

	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

(IF YOU ANSWERED "NO" TO QUESTION 1 AND/OR 2, YOU CAN NOT SUBMIT THIS APPLICATION)

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?		X
3. Been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
4. Been the subject of a board citation or an administrative action whether completed or pending in any state?	X	
5. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any of the numbered questions (3-5) above, include the following information & provide an explanation & documentation:

	State	Date:	Case #:		
Board Administrative Action: COMPLETED	CA	05/20/2014	4400		
Criminal Action:	State: CA	Date: 02/08/2011	Case #: TWV1002562	County: SAN BERNARDINO	Court: RANCHO CUCAMONGA

The Nevada Legislature requires that we include the following questions as part of all applications (NRS639.129)

	Yes	No
Are you the subject of a court order for the support of a child?	☐	X
IF you marked YES to the question, above are you in compliance with the court order?	☐	☐

I hereby certify that the information furnished on this document is true and correct. I agree to abide by all the statutes, rules and regulations governing pharmaceutical technicians and understand that a violation of any such statutes, rules and regulations may be grounds for suspension or revocation of this permit. I understand that Nevada law requires a licensed PT who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Antonio Madrid
Original Signature, no copies or stamps accepted

03/22/2021
Date

Board Use Only: Date Processed: _____ **Amount:** 50

3/22/2021

Antonio Madrid CPhT
[redacted] Ruby Avenue
Redlands, CA 92374

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

Dear Nevada State Board of Pharmacy,

I am writing this letter to explain why I marked "Yes" to Questions #3 & #4 on the application for Pharmaceutical Technician.

Question #3: I marked "Yes" because 10 years ago on February 8, 2011 in Rancho Cucamonga, CA (San Bernardino County) I was convicted of Misdemeanor-VC23152(A)-Driving Under the Influence (Case# TWV1002562) and was given a 67 month Probation term that ended on August 27, 2016. While on Probation also attended a court approved 1st Offender drinking and driving program for 3 months and paid a fine of 1,805.00. Submitted proof of completion on January 27, 2014. For further information, please see documentation included.

Question #4: I marked "Yes" because on May 20, 2014 Case #4400 was filed by the California Board of Pharmacy against me for (i)Failure to Disclose 1996 Petty Theft Conviction, (ii) February 8, 2011, DUI Conviction, and (iii) June 11, 2011 Alcohol Related Arrest. Completed 3-year Probation period, provided satisfactory proof of Certification (PTCB) and paid 3,405.00 in fines. Under Probation, Reported, and Interviewed with the Board Inspector Quarterly (in-person). License Status: Clear. Expiration Date: June 30,2021. For further information, please see documentation included.

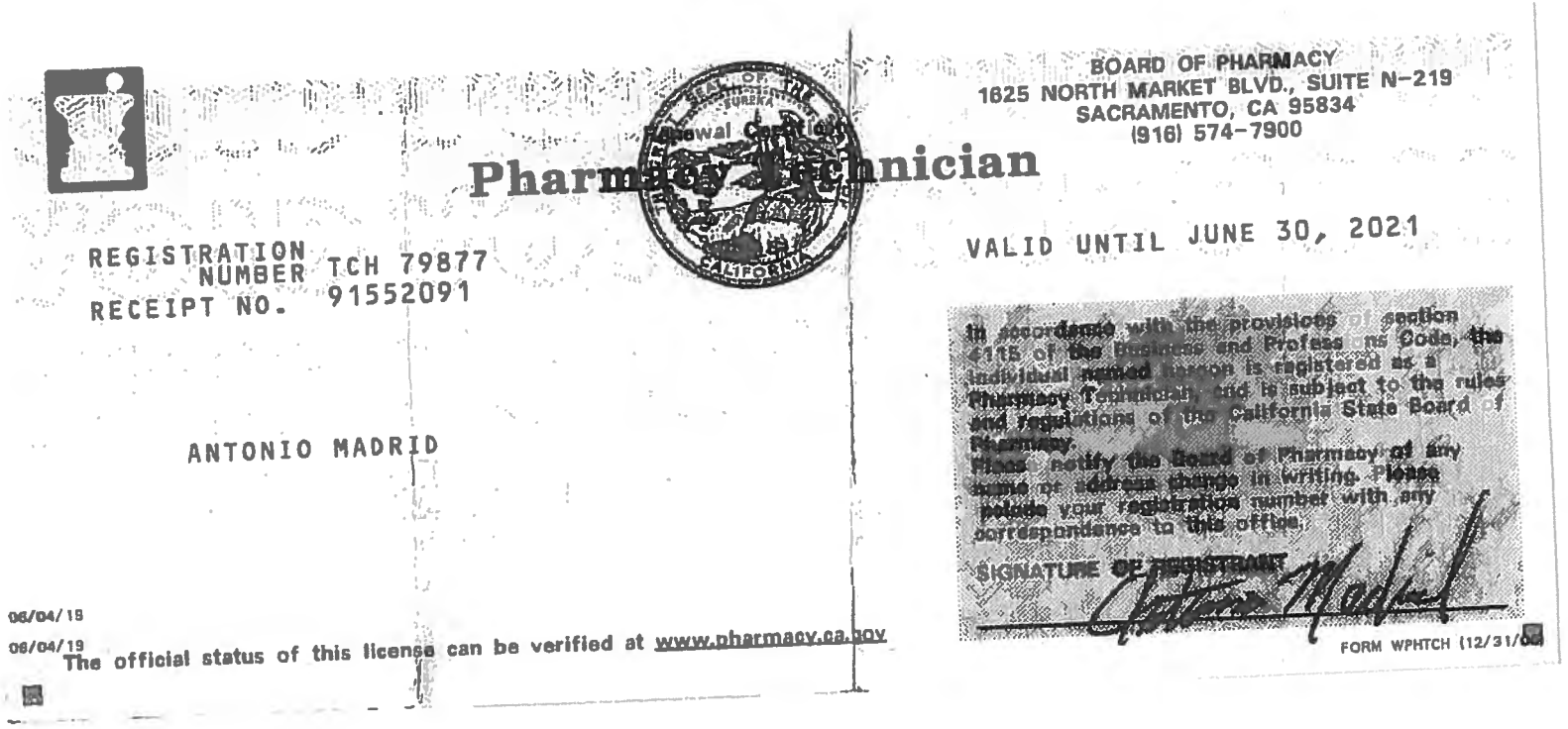
Included in the Board of Pharmacy court papers is a letter of Personal recommendation from Pharmacist Mahshid Aalam Pharm D. from AIDS Healthcare Foundation were I am still employed working for same employer AIDS healthcare Foundation and working same pharmacist who wrote letter of recommendation back in 2014. I have been humbled and hardworking, committed to excellence in my role as a Pharmacy technician. I have been given the opportunity to grow and assist my current employer (AIDS Healthcare Foundation) in Nevada and would like to apply for Pharmacy technician.

Sincerely,

Antonio Madrid

Antonio Madrid CPhT
AHF Pharmacy-Downtown
1414 South Grand Avenue Suite 801
Los Angeles, CA 90015
Tel. 213-741-5271 ext. 5552
Fax. 888-972-5391
Cell. [redacted]

1704



Renewal Certificate

Pharmacy Technician

BOARD OF PHARMACY
1625 NORTH MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834
(916) 574-7900

REGISTRATION NUMBER TCH 79877
RECEIPT NO. 91552091

VALID UNTIL JUNE 30, 2021

ANTONIO MADRID

In accordance with the provisions of section 4115 of the Business and Professions Code, the individual named hereon is registered as a Pharmacy Technician, and is subject to the rules and regulations of the California State Board of Pharmacy.

Please notify the Board of Pharmacy of any name or address change in writing. Please include your registration number with any correspondence to this office.

SIGNATURE OF REGISTRANT

06/04/19

06/04/19 The official status of this license can be verified at www.pharmacy.ca.gov

FORM WPHTCH (12/31/04)

COPY

1705

PHARMACY TECHNICIAN CERTIFICATION BOARD

Antonio Madrid

10063244 - CPhT

Certified September 29, 2014

Apply by September 01, 2022

Expires on September 30, 2022

PTCB

ptcb.org

copy

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

Case Information

TWV1002562 | The People of the State of California vs. ANTONIO MADRID

Case Number	Court	
TWV1002562	Rancho Cucamonga Criminal	
File Date	Case Type	Case Status
12/01/2010	Misdemeanor	Probation

Party

Plaintiff
The People of the State of California

Defendant
MADRID, ANTONIO

DOB
XX/XX/XXXX

Active Attorneys
Pro Se

Charge

Charges
MADRID, ANTONIO

	Description	Citation	Statute	Level	Date
1	VC23152(A)-M: Driving Under the Influence	95258MM	23152(A)	Misdemeanor	08/29/2010
2	VC23152(B)-M: Driving under the influence alcohol/0.08% or more	95258MM	23152(B)	Misdemeanor	08/29/2010

Disposition Events

02/08/2011 Plea

Judicial Officer
Pro Tem, Judge

1	VC23152(A)-M: Driving Under the Influence	No Contest

08/27/2013 Disposition

Judicial Officer
Gilbert, Ronald J

1	VC23152(A)-M: Driving Under the Influence	Convicted

02/08/2011 Disposition

Judicial Officer
Gilbert, Ronald J

2	VC23152(B)-M: Driving under the influence alcohol/0.08% or more	Dismissed

02/08/2011 Sentenced

1	VC23152(A)-M: Driving Under the Influence	Sentenced

Probation

Type: **Summary Probation (Court)**

Start Date: **02/08/2011**

Term: **67 Months**

End Date: **08/27/2016**

Status

Status	Date	Comment
Active	02/08/2011	

Comment: **1) VIOLATE NO LAW OTHER THAN MINOR TRAFFIC. (TMVNL) 2) PAYABLE AT A RATE OF $40.00 PER MONTH (TMPF1) COMMENCING 03/14/2011; (TMPF2) PLUS $35.00 COLLECTION FEE; (TMPF3) PAY A FINE OF $1805.00 TO THE COURT; (TMPFC) 3) ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 10/01/2013, SUBMIT PROOF OF COMPLETION TO COURT BY 10/01/2014 IN CLERK OFFICE PRF (TMAP) 4) NOT DRIVE MOTOR VEHICLE UNLESS PROPERLY LICENSED. (TMMVL) 5) NOT DRIVE A MOTOR VEHICLE UNLESS PROPERLY INSURED. (TMMVI) 6) NOT DRIVE A MOTOR VEHICLE WITH A MEASURABLE AMOUNT OF ALCOHOL IN YOUR SYSTEM. (TMMBA) 7) SUBMIT TO A BLOOD ALCOHOL TEST UPON REQUEST OF ARRESTING OFFICER. (TMBBU)**

Events and Hearings

12/01/2010 New Filed Case

12/03/2010 Amended Citation Notice Attached To Citation. ▾

Comment
AMENDED CITATION NOTICE ATTACHED TO CITATION.

12/21/2010 Arraignment ▾

Original Type
Arraignment

Judicial Officer
Gilbert, Ronald J

Hearing Time
12:30 PM

Result
Held

12/21/2010 Legacy Minutes ▾

Comment
- RJG, C-COMMISSIONER CLERK: CI-CHYRILL INCIONG DEFENDANT NOT PRESENT. - PROCEEDINGS ACTION CAME ON FOR ARRAIGNMENT DEFENDANT FAILS TO APPEAR AS PREVIOUSLY ORDERED. - CUSTODY STATUS CASE CUSTODY - FUGITIVE ========== MINUTE ORDER END ========== 0

02/08/2011 Arraignment ▾

Original Type
Arraignment

Judicial Officer
Gilbert, Ronald J

Hearing Time
8:30 AM

Result
Continued Court's motion

02/08/2011 Legacy Minutes ▾

Comment
- RJG, C-COMMISSIONER CLERK: VYG-VALERIE GUTIERREZ BAILIFF K OLIVA DEFENDANT PRESENT. (WALK IN APPEARANCE) - PROCEEDINGS ACTION CAME ON FOR ARRAIGNMENT DEFENDANT IS ADVISED OF CONSTITUTIONAL AND STATUTORY RIGHTS. DEFENDANT ARRAIGNED. - PLEA INFORMATION DEFENDANT PLEADS NOLO CONTENDERE TO COUNT(S): 1. THE COURT ACCEPTS THE PLEA AND FINDS THE DEFENDANT GUILTY AS CHARGED. - DISMISSALS COUNT(S) 2 DISMISSED IN THE INTEREST OF JUSTICE. - THE COURT, AFTER READVISEMENT OF EACH OF THESE RIGHTS, FINDS THAT THE DEFENDANT UNDERSTANDS THE CHARGE(S), THE POSSIBLE PENALTIES, RIGHT AGAINST SELF-INCRIMINATION, TO CONFRONT AND CROSS EXAMINE WITNESSES, TO A PUBLIC AND SPEEDY TRIAL, TO JURY TRIAL, TO HAVE AN ATTORNEY PRESENT AT ALL STAGES OF THE PROCEEDINGS AND TO THE PUBLIC DEFENDER IF INDIGENT AND TO THE COMPULSORY PROCESS OF THE COURT TO SUBPOENA WITNESSES. COURT FINDS PLEA IS BASED ON FACT. DEFENDANT IS INFORMED OF HIS/HER RIGHT TO BE SENTENCED NO EARLIER THAN SIX HOURS NOR ANY LATER THAN FIVE DAYS AFTER HE/SHE HAS ENTERED HIS/HER PLEA OF GUILTY OR NOLO CONTENDERE OR FOUND GUILTY. THE COURT FINDS THAT HE/SHE KNOWINGLY, FREELY AND EXPRESSLY WAIVES THAT RIGHT. TAHL WAIVER FILED. STIP RE: JUDGE PRO TEMPORE AND ADVISEMENT OF RIGHTS; WAIVER AND PLEA FORM FILED. DEFENDANT WAIVES FORMAL ARRAIGNMENT FOR PRONOUNCEMENT OF JUDGMENT AND STATES THERE IS NO LEGAL CAUSE WHY JUDGMENT SHOULD NOT NOW BE PRONOUNCED. - SENTENCING INFORMATION FOR ALL CHARGES. PRONOUNCEMENT OF JUDGMENT IS ORDERED WITHHELD AND CONDITIONAL AND REVOCABLE RELEASE IS GRANTED FOR A PERIOD OF 36 MONTH(S) ON THE FOLLOWING TERMS AND CONDITIONS: VIOLATE NO LAW OTHER THAN MINOR TRAFFIC. PAY A FINE OF $1805.00 TO THE COURT; NUMBER OF CONVICTED COUNTS 001 WITH A CONVICTION ASSESSMENT FEE INCLUDED. PLUS $35.00 COLLECTION FEE; PAYABLE AT A RATE OF $40.00 PER MONTH COMMENCING 03/14/2011; PAYMENT PLAN NOTICE ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 03/14/2011, SUBMIT PROOF OF COMPLETION TO COURT BY 08/08/2011 IN CLERK OFFICE PRF NOT DRIVE MOTOR VEHICLE UNLESS PROPERLY LICENSED. NOT DRIVE A MOTOR VEHICLE UNLESS PROPERLY INSURED. NOT DRIVE A MOTOR VEHICLE WITH A MEASURABLE AMOUNT OF ALCOHOL IN YOUR SYSTEM. SUBMIT TO A BLOOD ALCOHOL TEST UPON REQUEST OF ARRESTING OFFICER. DEFENDANT ACCEPTS PROBATION AND IS GIVEN A COPY OF THE TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

02/08/2011 Defendant Waived Right to Trial by Jury

02/08/2011 Defendant advised of Charges and Direct Consequences of Plea

02/08/2011 Defendant Waived Right to Confront And Cross Examine Witness

02/08/2011 Defendant Waived Privilege Against Compulsory Self-Incrimina

02/08/2011 Court Found Plea Was Knowledgeable, Intelligently Made,

02/08/2011 Conviction Certified By Clerk of the Court

02/08/2011 Defendant Waived Counsel (for case)

02/18/2011 Operator Changed Date to Pay ▾

Comment
OPERATOR AUTCK CHANGED DTP FROM 03/14/11 TO 04/14/11.

02/18/2011 AutoCheck - Pay Plan Installment Received ▾

Comment
AUTOCHECK PAY PLAN - FULL INSTALLMENT RECEIVED WITH BALANCE DUE.

02/18/2011 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

02/24/2011 Conversion event

Comment
PAYMENT PLAN NOTICE PRINTED

03/03/2011 Modification of Probation

Original Type
Modification of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
08:30 AM

Result
Continued Court's motion

03/03/2011 Legacy Minutes

Comment
- RJG, C-COMMISSIONER CLERK: CI-CHYRILL INCIONG BAILIFF K OLIVA DEFENDANT PRESENT NOT IN CUSTODY. - PROCEEDINGS ACTION CAME ON FOR MODIFICATION OF PROBATION - PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). FOR ALL CHARGES. TERM NUMBER 3 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 04/21/2011, SUBMIT PROOF OF COMPLETION TO COURT BY 04/21/2012 IN CLERK OFFICE PRF - DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

04/19/2011 Operator Changed Date to Pay

Comment
OPERATOR SPERE CHANGED DTP FROM 04/14/11 TO 05/14/11.

04/19/2011 Defendant Made a Payment

Comment
DEFENDANT MADE A PAYMENT OF $40.00.

04/19/2011 Payment Rcvd - Payment Plan

Comment
PAYMENT RECEIVED - PAYMENT PLAN NOTICE PRINTED

04/25/2011 Modification of Probation

Original Type
Modification of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
8:30 AM

Result
Continued Court's motion

04/25/2011 Legacy Minutes

Comment
RJG, C-COMMISSIONER CLERK: CI-CHYRILL INCIONG BAILIFF K OLIVA DEFENDANT PRESENT. (WALK IN APPEARANCE) - PROCEEDINGS ACTION CAME ON FOR MODIFICATION OF PROBATION DEFENDANT ADMITS VIOLATION(S) OF PROBATION, AS TO TERM(S) 03. DEFENDANT WAIVES RIGHT TO HAVE A FORMAL HEARING, TO PRESENT EVIDENCE, CROSS-EXAMINE WITNESSES, SUBPOENA WITNESSES, AND TO REMAIN SILENT. VICKERS HEARING WAIVED. PROBATION REVOKED AND REINSTATED. PROBATION IS EXTENDED TO EXPIRE ON 04/25/2014. PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). TERM NUMBER 3 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 05/31/2011, SUBMIT PROOF OF COMPLETION TO COURT BY 05/31/2012 IN CLERK OFFICE PRF DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

05/13/2011 Payment Rcvd - Payment Plan

Comment
PAYMENT RECEIVED - PAYMENT PLAN NOTICE PRINTED

05/13/2011 Operator Changed Date to Pay

Comment
OPERATOR RRIZZ CHANGED DTP FROM 05/14/11 TO 06/14/11.

05/13/2011 Defendant Made a Payment

Comment
DEFENDANT MADE A PAYMENT OF $40.00.

06/02/2011 Modification of Probation

Original Type
Modification of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
08:30 AM

Result
Continued Court's motion

06/02/2011 Legacy Minutes

Comment
- RJG, C-COMMISSIONER CLERK: A5474-MARLENE GALINDO BAILIFF R LONG - APPEARANCES DEFENDANT PRESENT NOT IN CUSTODY. - PROCEEDINGS ACTION CAME ON FOR VIOLATION OF PROBATION DEFENDANT ADMITS VIOLATION(S) OF PROBATION, AS TO TERM(S) -3. DEFENDANT WAIVES RIGHT TO HAVE A FORMAL HEARING, TO PRESENT EVIDENCE, CROSS-EXAMINE WITNESSES, SUBPOENA WITNESSES, AND TO REMAIN SILENT. VICKERS HEARING WAIVED. COURT ORDERS PROBATION REVOKED. PROBATION REINSTATED. FOR ALL CHARGES. PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). TERM NUMBER 3 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 07/05/2011, SUBMIT PROOF OF COMPLETION TO COURT BY 09/30/2011 IN CLERK OFFICE PRF DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

06/17/2011 Operator Changed Date to Pay

Comment
OPERATOR CGOME CHANGED DTP FROM 06/14/11 TO 07/14/11.

06/17/2011 Defendant Made a Payment

Comment
DEFENDANT MADE A PAYMENT OF $40.00.

06/17/2011 Payment Rcvd - Payment Plan

Comment
PAYMENT RECEIVED - PAYMENT PLAN NOTICE PRINTED

07/15/2011 Operator Changed Date to Pay

Comment
OPERATOR AYOUN CHANGED DTP FROM 07/14/11 TO 08/14/11.

07/15/2011 Defendant Made a Payment

Comment
DEFENDANT MADE A PAYMENT OF $40.00.

07/15/2011 Payment Rcvd - Payment Plan

Comment
PAYMENT RECEIVED - PAYMENT PLAN NOTICE PRINTED

07/20/2011 Modification of Probation

Original Type
Modification of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
08:30 AM

Result
Continued Court's motion

07/20/2011 Legacy Minutes ▾

Comment
- RJG, J-JUDGE CLERK: CI-CHYRILL INCIONG BAILIFF K. OLIVA - APPEARANCES DEFENDANT PRESENT NOT IN CUSTODY. - PROCEEDINGS ACTION CAME ON FOR MODIFICATION OF PROBATION - DEFENDANT ADMITS VIOLATION(S) OF PROBATION, AS TO TERM(S) 3. DEFENDANT WAIVES RIGHT TO HAVE A FORMAL HEARING, TO PRESENT EVIDENCE, CROSS-EXAMINE WITNESSES, SUBPOENA WITNESSES, AND TO REMAIN SILENT. VICKERS HEARING WAIVED. - PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). TERM NUMBER 3 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 08/24/2011, SUBMIT PROOF OF COMPLETION TO COURT BY 08/24/2012 IN CLERK OFFICE PRF - DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

08/16/2011 Operator Changed Date to Pay ▾

Comment
OPERATOR AUTCK CHANGED DTP FROM 08/14/11 TO 09/14/11.

08/16/2011 AutoCheck - Pay Plan Installment Received ▾

Comment
AUTOCHECK PAY PLAN - FULL INSTALLMENT RECEIVED WITH BALANCE DUE.

08/16/2011 Conversion event ▾

Comment
FINE PAYMENT OF 40.00 RECEIVED

09/12/2011 Conversion event ▾

Comment
FINE PAYMENT OF 40.00 RECEIVED

10/12/2011 Conversion event ▾

Comment
FINE PAYMENT OF 40.00 RECEIVED

11/13/2011 Conversion event ▾

Comment
FINE PAYMENT OF 40.00 RECEIVED

12/18/2011 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

01/17/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

02/10/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

03/09/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

04/23/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

04/23/2012 Delinquent Misdemeanor Case

05/21/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

06/15/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

07/27/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

08/13/2012 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

09/10/2012 Ex Parte Hearing

Original Type
Ex Parte Hearing

Judicial Officer
Ferguson, Jon

Hearing Time
04:00 PM

Result
Held

09/10/2012 Note:

Comment
PROOF CAL

09/10/2012 Defendant Failed To File Proof Of Enrollment/Completion

Comment
DEFENDANT FAILED TO FILE PROOF OF ENROLLMENT/COMPLETION FOR ALCOHOL PROGRAM.

09/10/2012 Legacy Minutes

Comment
JDF, J-JUDGE CLERK: CC157-LAURA GONZALEZ DEFENDANT NOT PRESENT. - PROCEEDINGS IT BEING ALLEGED THAT DEFENDANT HAS FAILED TO COMPLY WITH TERM 3 OF HIS/HER PROBATION ORDER. COURT ORDERS PROBATION REVOKED FOR THE PURPOSES OF RETAINING JURISDICTION. - CUSTODY STATUS CASE CUSTODY - FUGITIVE ========== MINUTE ORDER END ========== 0

12/12/2012 Conversion event

Comment
FINE PAYMENT OF 160.00 RECEIVED

12/18/2012 Request For Action - No Appearance

Original Type
Request For Action - No Appearance

Judicial Officer
Bilash, Colin J

Hearing Time
04:00 PM

Result
Held

12/18/2012 Legacy Minutes

Comment
CJB, J-JUDGE CLERK: CC142-SABRINA VAUGHN DEFENDANT NOT PRESENT. - PROCEEDINGS REQUEST TO ISSUE A WRIT RECEIVED FROM COURT COMPLIANCE. - REQUEST TO ISSUE WRIT IS

DENIED. - FINDINGS/ADVISALS: - COURT COMPLIANCE NOTIFIED. - CUSTODY STATUS CASE CUSTODY - FUGITIVE ========== MINUTE ORDER END ========== 0

01/17/2013 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

02/14/2013 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

03/05/2013 Conversion event

Comment
FINE PAYMENT OF 700.00 RECEIVED

04/16/2013 Conversion event

Comment
FINE PAYMENT OF 40.00 RECEIVED

05/18/2013 Conversion event

Comment
FINE PAYMENT OF 45.00 RECEIVED

06/12/2013 Hearing on Revocation of Probation

Original Type
Hearing on Revocation of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
08:30 AM

Result
Continued Court's motion

06/12/2013 Defendant Made a Payment

Comment
DEFENDANT MADE A PAYMENT OF $95.00.

06/12/2013 Case Reassigned to Another District

Comment
CASE REASSIGNED TO RS- RANCHO DISTRICT.

06/12/2013 Legacy Minutes

Comment
RJG, C-COMMISSIONER CLERK: CI-CHYRILL INCIONG BAILIFF M SMITH - APPEARANCES DEPUTY DISTRICT ATTORNEY NOT PRESENT. DEFENDANT PRO PER. DEFENDANT PRESENT NOT IN CUSTODY. - PROCEEDINGS ACTION CAME ON FOR VIOLATION OF PROBATION - DEFENDANT ADVISED OF HIS/HER RIGHTS. DEFENDANT WAIVES RIGHT TO HAVE A FORMAL HEARING, TO PRESENT EVIDENCE, CROSS-EXAMINE WITNESSES, SUBPOENA WITNESSES, AND TO REMAIN SILENT. VICKERS HEARING WAIVED. DEFENDANT ADMITS VIOLATION(S) OF PROBATION, AS TO TERM(S) 3. DEFENDANT IS FOUND TO BE IN VIOLATION OF PROBATION - PROBATION REINSTATED. PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). FOR ALL CHARGES. - PROBATION IS EXTENDED TO EXPIRE ON 06/12/2015. - TERM NUMBER 03 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 07/17/2013, SUBMIT PROOF OF COMPLETION TO COURT BY 07/17/2014 IN CLERK OFFICE PRF - DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

07/03/2013 Proof of Enrollment in Alcohol Program filed ▾

Comment
PROOF OF ENROLLMENT IN ALCOHOL PROGRAM FILED.

08/12/2013 Notice of Failure to Attend Alcohol Program ▾

Comment
NOTICE OF FAILURE TO ATTEND ALCOHOL PROGRAM FILED.

08/14/2013 Ex Parte Hearing ▾

Original Type
Ex Parte Hearing

Judicial Officer
Ferguson, Jon

Hearing Time
04:00 PM

Result
Held

08/14/2013 Legacy Minutes ▾

Comment
JDF, J-JUDGE CLERK: D6986-JESSICA JOANIS DEFENDANT NOT PRESENT. - PROCEEDINGS IT BEING ALLEGED THAT DEFENDANT HAS FAILED TO COMPLY WITH TERM 3 OF HIS/HER PROBATION ORDER. COURT ORDERS PROBATION REVOKED FOR THE PURPOSES OF RETAINING JURISDICTION. - CUSTODY STATUS CASE CUSTODY - FUGITIVE ========== MINUTE ORDER END ========== 0

08/27/2013 Hearing on Revocation of Probation ▾

Original Type
Hearing on Revocation of Probation

Judicial Officer
Gilbert, Ronald J

Hearing Time
08:30 AM

Result
Continued Court's motion

08/27/2013 Legacy Minutes

Comment
- RJG, C-COMMISSIONER CLERK: VYG-VALERIE GUTIERREZ BAILIFF ED CHAMPIN - APPEARANCES DEPUTY DISTRICT ATTORNEY NOT PRESENT. DEFENDANT PRESENT NOT IN CUSTODY. DEFENDANT PRO PER. - PROCEEDINGS ACTION CAME ON FOR VIOLATION OF PROBATION - DEFENDANT WAIVES RIGHT TO HAVE A FORMAL HEARING, TO PRESENT EVIDENCE, CROSS-EXAMINE WITNESSES, SUBPOENA WITNESSES, AND TO REMAIN SILENT. DEFENDANT ADMITS VIOLATION(S) OF PROBATION, AS TO TERM(S) 03. VICKERS HEARING WAIVED. - DEFENDANT IS FOUND TO BE IN VIOLATION OF PROBATION - PROBATION REINSTATED. PROBATION IS CONTINUED ON ORIGINAL TERMS AND CONDITIONS WITH THE FOLLOWING MODIFICATION(S). FOR ALL CHARGES. - PROBATION IS EXTENDED TO EXPIRE ON 08/27/2016. - TERM NUMBER 03 IS MODIFIED AS FOLLOWS: ATTEND CO APPROVED (1ST OFF) ALCOHOL PROG FOR 3 MONTHS. ENROLL BY 10/01/2013, SUBMIT PROOF OF COMPLETION TO COURT BY 10/01/2014 IN CLERK OFFICE PRF - DEFENDANT ACCEPTS MODIFICATION OF TERMS AND CONDITIONS. - CUSTODY STATUS CASE CUSTODY - PROBATION. ========== MINUTE ORDER END ========== 0

10/01/2013 Proof filed

Comment
PROOF OF REINSTATEMENT IN ALCOHOL PROGRAM FILED

01/27/2014 Proof of Completion of Alcohol Program filed (AB541)

Comment
PROOF OF COMPLETION OF ALCOHOL PROGRAM FILED.

Financial

MADRID, ANTONIO

Total Financial Assessment	$1,840.00
Total Payments and Credits	$1,840.00

2/8/2011	Transaction Assessment			$1,805.00
2/8/2011	Transaction Assessment			$35.00
2/18/2011	Counter Payment	Receipt # 20110218-1120	MADRID, ANTONIO	($40.00)
4/19/2011	Counter Payment	Receipt # 20110419-2312	MADRID, ANTONIO	($40.00)
5/13/2011	Counter Payment	Receipt # 20110513-1493	MADRID, ANTONIO	($40.00)
6/17/2011	Counter Payment	Receipt # 20110617-0537	MADRID, ANTONIO	($40.00)

7/15/2011	Counter Payment	Receipt # 20110715-0335	MADRID, ANTONIO	($40.00)
8/16/2011	Counter Payment	Receipt # 20110816-0444	MADRID, ANTONIO	($40.00)
9/12/2011	Counter Payment	Receipt # 20110912-2216	MADRID, ANTONIO	($40.00)
10/12/2011	Counter Payment	Receipt # 20111012-3937	MADRID, ANTONIO	($40.00)
11/13/2011	Counter Payment	Receipt # 20111113-0210	MADRID, ANTONIO	($40.00)
12/18/2011	Counter Payment	Receipt # 20111218-0010	MADRID, ANTONIO	($40.00)
1/17/2012	Counter Payment	Receipt # 20120117-1346	MADRID, ANTONIO	($40.00)
2/10/2012	Counter Payment	Receipt # 20120210-1794	MADRID, ANTONIO	($40.00)
3/9/2012	Counter Payment	Receipt # 20120309-1752	MADRID, ANTONIO	($40.00)
4/23/2012	Counter Payment	Receipt # 20120423-3248	MADRID, ANTONIO	($40.00)
5/21/2012	Counter Payment	Receipt # 20120521-0632	MADRID, ANTONIO	($40.00)
6/15/2012	Counter Payment	Receipt # 20120615-3595	MADRID, ANTONIO	($40.00)
7/27/2012	Counter Payment	Receipt # 20120727-3412	MADRID, ANTONIO	($40.00)
8/13/2012	Counter Payment	Receipt # 20120813-1278	MADRID, ANTONIO	($40.00)
12/12/2012	Counter Payment	Receipt # 20121212-3074	MADRID, ANTONIO	($160.00)
1/17/2013	Counter Payment	Receipt # 20130117-2043	MADRID, ANTONIO	($40.00)
2/14/2013	Counter Payment	Receipt # 20130214-2716	MADRID, ANTONIO	($40.00)
3/5/2013	Counter Payment	Receipt # 20130305-3600	MADRID, ANTONIO	($700.00)
4/16/2013	Counter Payment	Receipt # 20130416-3430	MADRID, ANTONIO	($40.00)
5/18/2013	Counter Payment	Receipt # 20130518-0558	MADRID, ANTONIO	($45.00)
6/12/2013	Counter Payment	Receipt # 20130612-1101	MADRID, ANTONIO	($95.00)
6/12/2013	Transaction Assessment			$0.00
6/12/2013	Transaction Assessment			$0.00
6/12/2013	Transaction Assessment			$0.00

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ANTONIO MADRID Pharmacy Technician Registration No. TCH 79877, Respondent.	Case No. 4400 OAH No. 2013110634

PROPOSED DECISION

Administrative Law Judge Roy W. Hewitt, Office of Administrative Hearings, State of California, heard this matter in San Bernardino, California, on May 20, 2014.

Deputy Attorney General Kevin J. Rigley represented complainant.

Antonio Madrid (respondent) represented himself.

The matter was submitted on May 20, 2014.

FACTUAL FINDINGS

1. The Accusation against respondent was filed by Virginia Herold (complainant), while acting in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs, State of California (the board).

2. On January 7, 2008, the board issued Pharmacy Technician Registration No. TCH 79877 to respondent. Respondent's registration was in full force and effect at all relevant times.

Respondent's 1996 Petty Theft Conviction

3. On April 16, 1996, in Los Angeles County Superior Court, case number 6CR00215, respondent was convicted of violating California Penal Code section 484, subdivision (a) (petty theft), a misdemeanor. Respondent's conviction involved dishonesty

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ANTONIO MADRID** [redacted]Ruby Ave. Redlands, CA 92374 Pharmacy Technician Registration No. TCH 79877 Respondent.	Case No. 4460 OAH No. 2013110634

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on August 11, 2014.

It is so ORDERED on July 11, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STAN C. WEISSER
Board President

and was for a crime that is substantially related to the qualifications, functions and duties of a pharmacy technician.

4. The facts underlying respondent's conviction are as follows: on April 15, 1996, respondent, who was 19 years old, entered a Thrifty's Store in Los Angeles, California; respondent was seen concealing an item of merchandise under his shirt; respondent attempted to leave the store without paying for the merchandise and was detained by store security; a bottled of whiskey was found concealed in respondent's waistband; and respondent was arrested for shoplifting.

5. As a result of his conviction, respondent was placed on one year of summary probation on certain terms and conditions.

6. Respondent successfully completed his criminal probation.

Respondent's Failure to Disclose His 1996 Petty Theft Conviction

7. On October 23, 2007, respondent signed, and thereafter submitted to the board, his application for licensure/registration. Question number 6 of the application asked: "Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States or any state laws or local ordinances?" Respondent falsely answered the question by checking the "No" box.

Respondent's February 8, 2011, DUI conviction

8. On February 8, 2011, in San Bernardino County Superior Court, case number TWV1002562, respondent was convicted of violating California Vehicle Code section 23152, subdivision (a) (driving under the influence of alcohol (DUI)), a misdemeanor that is substantially related to the qualifications, functions and duties of a licentiate.

9. As a result of the DUI conviction, respondent was placed on three years of summary probation under certain terms and conditions.

10. The board was advised of respondent's DUI conviction and elected to issue respondent a warning letter as the appropriate level of discipline.

Respondent's June 11, 2011, Alcohol-Related Arrest

11. On June 11, 2011, a California Highway Patrol officer detained respondent for suspicion of DUI. The officer detected the strong odor of alcohol on respondent's breath. Additionally, respondent had red, blood-shot, watery eyes. Accordingly, the officer used a Preliminary Alcohol Screening (PAS) device to test respondent's blood alcohol level. The PAS tests indicated that respondent's blood alcohol content was 0.17%. Consequently, respondent was arrested for DUI.

12. On October 12, 2011, a criminal complaint was filed against respondent. The complaint charged respondent with violating California Vehicle Code sections 23152, subdivision (a) (DUI), and 23152, subdivision (b) (driving while having 0.08% or more, by weight, of alcohol in the blood), misdemeanors.

13. Respondent's "speedy trial rights" were violated when the complaint against him was not timely prosecuted; therefore, on December 11, 2013, all counts contained in the criminal complaint against respondent were dismissed, in furtherance of justice, pursuant to California Penal Code section 1385.

Respondent's Evidence

14. Respondent admitted that he falsely answered the prior conviction question in his 2007 application for licensure because he was afraid his application would be denied. When respondent saw the prior conviction question on the application, he "panicked" and checked the "No" box instead of disclosing his 1996 petty theft conviction.

15. Respondent's alcohol related arrests occurred in 2011, within five months of each other. At the time, respondent and his wife were experiencing marital difficulties and were considering separating. Respondent turned to alcohol "as an answer." Respondent stopped drinking alcoholic beverages after his June 11, 2011 arrest.

16. Respondent and his wife have resolved their marital issues and respondent is now in a stable home environment. Respondent's wife does not drink alcohol and she supports respondent's sobriety.

17. Respondent has been working as a pharmacy technician at the AIDS Healthcare Foundation located in downtown Los Angeles, California. Respondent has been working at the AIDS Healthcare Foundation for the past 10 years. Respondent presented two character reference letters from pharmacists who work with him at the AIDS Healthcare Foundation. Both of the pharmacists attested to the fact that respondent is a trusted and valued pharmacy technician and that he has had no patient complaints. Mahshid Aalam wrote:

> This letter is a personal recommendation for Mr. Antonio Madrid. I have worked with Antonio for more than 10 years, and have always enjoyed his quality of work, his honesty, ethics, and humor. Antonio is one of the pharmacy technician's [sic] I know I can rely on to get the job completed. Antonio is always on time, and takes his work serious[ly]. Antonio also has an excellent attitude and our patients love him. He is a team player and a leader. Antonio represents AHF like we want our patients to experience health care. (Exh. E)

18. Respondent's wife testified as follows: she has known respondent since she was 17 years old; she and respondent were high school sweethearts; she "despises" alcohol and, since respondent's 2011 arrest, he has become a "changed man;" she and respondent "stay away from activities that involve alcohol;" respondent has a "great record" as a pharmacy technician; her grandmother is very ill and is now living with respondent and her; she is a graphic design artist but finds it difficult to devote enough time to work to make enough money to make ends meet; due to financial difficulties, her student loans are on hold, as are the couple's utility bills; respondent is dedicated to his job and the patients at the Aids center; and, respondent has aspirations of eventually becoming a pharmacist.

Evaluation of the Evidence

19. Respondent was truthful and brutally honest during his testimony. He did not make any excuses for failing to disclose his 1996 conviction in his 2007 application for licensure; rather, he admitted he intentionally failed to disclose his 1996 conviction due to his fear of having his application denied. Respondent expressed true remorse for having given in to temptation by attempting to conceal his conviction. Respondent readily acknowledged that truthfulness and honesty are attributes that must be possessed by licentiates, and he convincingly established that his single act of dishonesty represented an isolated incident without likelihood of recurrence.

20. Respondent had two arrests that involved incidents reflecting alcohol abuse; however, it does not seem that respondent is an alcoholic. Respondent is willing to refrain from drinking alcohol as a condition of probation if he is granted probation.

21. There was no evidence that respondent posed a danger to the AIDS center patients. In fact, the evidence revealed that respondent is well respected by patients, supervisors, and fellow employees.

Costs

22. The actual and reasonable costs of the investigation and enforcement of this case total $3,405.

LEGAL CONCLUSIONS

1. Cause exists for discipline of respondent's Pharmacy Technician Registration pursuant to Business and Professions Code sections 490 and 4301, subdivision (l), in conjunction with California Code of Regulations, title 16, section 1770, because, as set forth in the findings, respondent was convicted of crimes that are substantially related to the qualifications, functions and duties of a licentiate/registrant.

2. Cause exists for discipline of respondent's Pharmacy Technician Registration pursuant to Business and Professions Code section 4301, subdivision (f), because, as set forth

in the findings, respondent committed acts involving dishonesty and deceit with the intent to substantially benefit himself.

3. Cause exists for discipline of respondent's Pharmacy Technician Registration pursuant to Business and Professions Code section 4301, subdivision (h), because, as set forth in the findings, respondent used alcoholic beverages in an extent or manner dangerous to himself and the public.

4. Cause exists for discipline of respondent's Pharmacy Technician Registration pursuant to Business and Professions Code section 4301, subdivision (g), because, as set forth in the findings, respondent knowingly made a false statement of fact to the board by failing to disclose his 1996 petty theft conviction in his 2007 application for licensure.

Costs

5. The reasonable costs of the investigation and enforcement of this case against respondent, recoverable pursuant to Business and Professions Code section 125.3, total $3,405. However, the findings established that respondent and his wife lack the ability to pay any cost recovery whatsoever. This factor is relevant under *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45.

Evaluation of the Appropriate Level of Discipline

6. The purpose of an administrative proceeding seeking the revocation or suspension of a professional license is not to punish the individual; the purpose is to protect the public from dishonest, immoral, disreputable or incompetent practitioners. (*Fahmy* v. *Medical Board of California* (1995) 38 Cal.App.4th 810, 817; *Ettinger* v. *Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

7. The acts that led to respondent's DUI incidents were situational. Respondent and his wife have resolved the situations that led to respondent's alcohol abuse, and respondent fully appreciates that fact that alcohol is not an answer to difficulties; rather, it just leads to further dangers and problems. Respondent no longer consumes alcohol and an order requiring abstention, as a condition of probation, will adequately protect the public. Respondent's single, immature act of dishonesty by failing to reveal his1996 petty theft conviction on his 2007 application represented an isolated act without likelihood of recurrence. Respondent was visibly embarrassed and humiliated by this omission and he expressed true remorse during his testimony. Finally, respondent is an excellent worker and is well respected by his current employer. Consequently, it would not be adverse to the public health, safety or welfare to place respondent's license/registration on probation for three years under terms and conditions designed to ensure public protection.

ORDER

Pharmacy Technician License/Registration number TCH 79877 is revoked; however, the revocation is stayed and respondent is placed on probation for three years upon the following terms and conditions:

1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he is certified, as defined by Business and Professions Code section 4202(a)(4), and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's license/registration or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of this decision and the terms, conditions and restrictions imposed on respondent by this decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read this decision and the terms and

conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of this in advance of respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read this decision and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether respondent is considered an employee, independent contractor or volunteer.

7. Reimbursement of Board Costs

Respondent is not required to reimburse the board for the costs of the investigation and enforcement of this case due to his inability to pay any awarded costs

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current pharmacy technician license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's pharmacy technician license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of 80 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of work" means calendar month during which respondent is not working for at least 80 hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least 80 hours as a pharmacy technician as defined by Business and Professions Code section 4115.

13. Violation of Probation

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

14. Abstain from Drugs and Alcohol Use

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled

substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

15. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician license will be fully restored.

Dated: June 12, 2014

Roy W. Hewitt

ROY W. HEWITT
Administrative Law Judge
Office of Administrative Hearings

8

8A

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy #206 – Reno, NV 89521

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE - PRESCRIBE

REGISTRATION FEE: FOR AUTHORITY TO PRESCRIBE DANGEROUS DRUGS ONLY $80.00 TOTAL
FOR AUTHORITY TO PRESCRIBE CONTROLLED SUBSTANCES $200.00 TOTAL
(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

First: Lindsay Middle: Kay Last: McComas
Home Address: [redacted] Oakbrook Ridge Ave
City: Henderson State: NV Zip Code: 89002
SS# or ITIN: [redacted] Date of Birth: [redacted] Sex: ☐ M or ☐ F
Telephone: [redacted] E-mail address: [redacted]

PRACTICING LOCATION (Required)

Practice Name (if any): Boulder Primary Care
Physical Address: 1252 Wyoming Street Suite #: 200
City: Boulder City State: NV Zip Code: 89005
Telephone: 702 791 0224 Fax: 702 791 0224
Nursing Board #: 841298 Issued: May 24, 21 Expires: Dec 04, 21

☒ **Check this box if you are an APRN who intends to apply for DEA Registration. Board Staff will notify DEA and you of the required information and provide a letter with your pending number to allow you to apply for the DEA in Nevada-(Do not apply to DEA before receiving your pending letter.) (Provide $200.00 Total Registration fee)**

You must have a current Nevada license with your respective BOARD before we will process this application. The Nevada license must remain current to keep the controlled substance registration.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
2. Been the subject of a board citation, administrative action whether completed or pending in any state?	☒	☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation & documentation:

Board Administrative Action.	State	Date:	Case #:
Agreement for monitoring	NV	8/27/2020	202007018

Criminal Action:	State	Date:	Case #:	County	Court
	NV	2/21/2019	19CR001601	Clark	Henderson
	NV	3/19/2020	19CR011221	Clark	Henderson

It is a violation of Nevada law to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

I understand that Nevada law requires a licensed APRN who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

[signature] 5/25/2021
Original Signature of APRN, no copies or stamps accepted Date

COLLABORATING PHYSICIAN's name (If required): _____

_____ _____
Original Signature of Collaborating Physician, no copies or stamps accepted Date

Board Use Only: Date Processed _____ **Amount** 200
Check # 1684

Nevada State Board of NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

LINDSAY KAY MCCOMAS

Wednesday, June 02 2021 11:23:36 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MCCOMAS, LINDSAY KAY	RN	TRN327186	Expired	12/22/2009	06/22/2010	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MCCOMAS, LINDSAY KAY	RN	RN65226	Active	04/15/2010	12/04/2021	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MCCOMAS, LINDSAY KAY	APRN-CNP	841298	Inactive	05/03/2021	05/24/2021	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 05/24/2021
  - Original Issuance Date: 05/03/2021
  - Current Issue Date: 05/03/2021
  - Certification expiration date: 04/19/2026

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
MCCOMAS, LINDSAY KAY	APRN-CNP	841298	Active - Prescribing	05/24/2021	12/04/2021	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 12/04/2021
  - Original Issuance Date: 05/24/2021
  - Current Issue Date: 05/24/2021
  - Certification expiration date: 04/19/2026

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

ORIGINAL RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

BEFORE THE NEVADA STATE BOARD OF NURSING

IN THE MATTER OF LINDSAY MCCOMAS LICENSED PROFESSIONAL NURSE NEVADA LICENSE NO. RN65226 RESPONDENT	AGREEMENT FOR MONITORING CASE NO. 202007018

This Agreement is hereby entered into between LINDSAY MCCOMAS, (RESPONDENT) and the NEVADA STATE BOARD OF NURSING, (BOARD).

It is hereby stipulated and agreed, by and between the parties to the above-entitled matter, that the following statements are true:

1. Respondent is aware of, understands, and has been advised of the effect of this Agreement, which Respondent herein has carefully read and fully acknowledges. No coercion has been exerted on the Respondent. Respondent acknowledges her right to an attorney at her own expense. Respondent has had the benefit at all times of obtaining advice from competent counsel of her choice.
2. Respondent understands the nature of the allegations under investigation by the Nevada State Board of Nursing. Respondent freely admits that she was convicted for driving under the influence of alcohol in 2019, a misdemeanor, and that she was convicted for domestic violence in 2020, a misdemeanor. Respondent acknowledges this conduct constitutes a violation of the Nevada Revised Statutes 632.347 (1)(b) criminal conviction. Respondent further acknowledges that such acts and admissions subject her to disciplinary action by the Board.
3. Respondent is aware of the Respondent's rights, including the right to a hearing on any charges and allegations, the right to an attorney at her own expense, the right to examine witnesses who would testify against her, the right to present evidence in her favor and call witnesses on her behalf, or to testify herself, the right to contest the charges and allegations, the right to reconsideration, appeal or any other type of formal judicial

review of this matter, and any other rights which may be accorded to her pursuant to the Nevada Administrative Procedures Act and the provisions of Chapter 632 of the Nevada Revised Statutes and the Nevada Administrative Code. **Respondent agrees to waive the foregoing rights upon acceptance of this Agreement by the Board.**

4. Respondent understands that the Board is free to accept or reject this Agreement, and if rejected by the Board, a disciplinary proceeding may be commenced. It is agreed that presentation to and consideration by the Board of such proposed Agreement, shall not disqualify the Board, or any of its members, from further participation, consideration, adjudication or resolution of these proceedings, and that no Board member shall be disqualified or challenged for bias therefore. This Agreement shall only become effective when both parties have duly executed it and unless so executed, this Agreement will not be construed as an admission.
5. This Agreement shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.
6. This Agreement shall cover any nursing license or certificate issued by the State of Nevada.

Based upon the foregoing stipulations and recitals, it is hereby agreed that the Board may issue the following decision and order:

DECISION AND ORDER

IT IS HEREBY ORDERED that Nevada Licensed Professional Nurse, license number RN65226, issued in the name of Lindsay McComas is placed on monitoring for a minimum of one (1) year with the following terms and conditions:

1. **COMPLETION OF COURSES**

Respondent shall take, and submit documentation of successful completion of the National Council of State Board of Nursing Understanding Substance Use Disorder in Nursing, and the Nevada Nurse Practice Act course **within (30) days** of acceptance and execution of the Agreement by the Board.

2. ABSTINENCE AND DRUG TESTING

Respondent shall abstain from the use of alcohol and all mood-altering drugs and controlled substances except when legally prescribed by a treating practitioner who is knowledgeable about the disease of addiction and the Respondent's history. This treatment must be reported to the Board, in writing, within seven (7) days, accompanied by documentation from the practitioner regarding the medical treatment and all other methods of alternative treatment having been tried first. The Board may require additional testing and reporting until Respondent documents sobriety after periods of prescribed drug use..

Respondent shall register with the Board approved drug-screening program and submit to random urine, blood or other tests for drugs of abuse and/or alcohol on the day requested by the drug testing company, her counselor, or representative of the Board. These tests shall occur no less than twenty-four (24) times per year and shall be treated as forensic specimens by a Board-approved laboratory. Respondent shall cause test results to be provided to the requesting party and the Board. Any confirmed positive finding shall be reported immediately to the Board. Changes in frequency of tests may be approved by the Compliance Coordinator and the Director of Nursing Practice.

3. REQUIREMENT TO ATTEND ORIENTATION AND MEET WITH THE BOARD OR STAFF

Respondent shall attend a **mandatory orientation** meeting within thirty days of execution of this Agreement by the Board to facilitate understanding and accountability of the terms and conditions of this Agreement as scheduled by the Compliance Coordinator. Upon request, Respondent shall meet with the Board or its representatives and cooperate with representatives of the Board in their supervision and investigation of Respondent's compliance with the terms and conditions of this Agreement.

4. FINANCIAL RESPONSIBILITY

Respondent shall be financially responsible for all requirements of this Agreement. Respondent has reviewed, and understands the potential costs associated with the stipulations

herein. Respondent understands these costs are subject to change and are her financial responsibility.

5. VIOLATIONS OF THIS AGREEMENT - CONSEQUENCES

Respondent acknowledges that if she violates any of the terms and conditions of this Agreement, the Board may revoke, or invoke other appropriate discipline against her license to practice nursing, subject to a hearing in accordance with the Nevada Nurse Practice Act for the purpose of establishing that there has, in fact, been a violation of the stipulations of this Agreement. Respondent acknowledges that any violation of the Nevada Nurse Practice Act, any dilute urine or positive drug screen may be considered a violation of this Agreement and subject to further action by the Board. A positive drug screen will result in immediate suspension of license. Suspension of license is considered disciplinary action and will become part of the Respondent's permanent record, will become public information, will be published with the list of disciplinary actions taken against licensees or holders of certificates, or any agency or another state which regulates the practice of nursing.

6. AGREEMENT TO SURRENDER LICENSE

In the event that a violation of the terms and conditions of this Agreement is alleged, Respondent agrees to surrender her license to the Executive Director, or the Director of Nursing Practice, if they so request, and refrain from practicing nursing until requirements have been met, violations resolved, or entry of a final order of the Board or a court of competent jurisdiction, whichever last occurs, regarding a potential violation. Respondent acknowledges that pursuant to NRS 632.405, this Agreement shall become a public record if an entry of a final order of the Board results in disciplinary action against her license for violation of this agreement.

7. COMPLETION AND TERMINATION OF MONITORING

Respondent acknowledges she is not eligible for early termination of this Agreement. The Agreement shall be terminated at the time the Board receives documentation verifying the Respondent's completion of all terms and conditions of the Agreement and when respondent receives notice of termination from the Board.

The NEVADA STATE BOARD OF NURSING retains jurisdiction in this case until all conditions have been met to the satisfaction of the Board.

Dated this 8 day of August, 2020

RESPONDENT
Lindsay McComas

Dated this 12 day of August, 2020

Kevin Murphy, Esq.

Accepted and approved this 27th day of August 2020

NEVADA STATE BOARD OF NURSING

By:
Cathy Dibauer, MSN, RN
Executive Director

HENDERSON MUNICIPAL COURT: SENTENCING ORDER

CITY OF HENDERSON, Plaintiff
VS.
Defendant

) Case #:
) DR #:
) ☐ DOMESTIC BATTERY / ☐ DUI:
) ☐ 1ST Offense / ☐ 2nd Offense
) ☐ OTHER (List Below):

☐ Guilty; ☐ Nolo; ☐ Adjudication Stayed ☐ Submitted on the Record,
Pending: ☐ Dismissal; ☐ Amendment to
Total Fines/AA Fees Imposed: $ Fines/Fees Suspended if compliant: $
☐ $35 DB Assessment Fee ☐ $60 Blood/Breath Test ☐ $50 Time Payment Setup Fee; ☐ $100 DUI Specialty Courts' Fee
Total Fines/Fees Due: $ Payments: $ per month or fine due in full by/beginning / /
Mail to: Henderson Municipal Court, PO Box 95050 - MS621, 243 Water Street, Henderson, NV 89009 On-line: www.cityofhenderson.com/municipal_court/

THE ABOVE REFERENCED DEFENDANT IS HEREBY SENTENCED TO THE FOLLOWING:

SENTENCING CONDITIONS

☐ **PROBATION / DIRECT SUPERVISION** (See Agreement & Rules Form) ☐ **PROBATION / INDIRECT SUPERVISION**

You must appear in person to Special Programs and Services (SPS), located at 243 Water Street, Lower Level, Henderson, NV immediately following court or upon the first business day following your release from custody, unless your intake was completed prior to your release. Failing to appear at the Special Programs and Services office, failing to comply with the court's order or receipt of a non-compliant report from any agency may result in immediate arrest for Probation Violation or a Bench Warrant issued for your arrest. You must report to Special Programs and Services as directed throughout the term of Supervision. You must provide correct contact information to Special Programs and Services and report any changes of that information immediately.

Probation / Supervision Expiration Date: / /

☒ DUI School
☐ Victim's Impact Panel
☐ Coroner's DUI Program
☒ Breath Ignition Interlock Device **
☐ Suspension of Registered Vehicles **
** Separate order required
☐ SCRAM Program weeks/months
☐ Install Prior to Release from Custody
☐ Report out-of-custody to SPS upon release for installation
☐ AA / NA / GA (or Acceptable Alternative)
☐ Sponsor required x/wk for wks
☐ DART Program
☒ weeks/month ☐ Duration
☐ Controlled Subst. including Marijuana
☐ Alcohol
☐ CAT Program weeks/months
☐ Coroner's Visitation Program (CVP)
☐ Restitution of $
Payable to City of Henderson on behalf of
☐ Via Monthly Payments $
☐ In Full by/beginning / /
(Submit payment to SPS)

☐ Domestic Battery Counseling (26 sessions, 1x/week)
☐ Long-Term Domestic Battery Counseling (52 sessions, 1x/week)
☐ Surrender, Sell or Transfer Firearms
** Separate order required
☐ Anger Control Management
☐ Level 1 ☐ Level 2
☐ Substance Abuse Counseling (SAC)
☐ Outpatient SAC ☐ Inpatient SAC
☐ Intensive outpatient SAC
☐ Group / ☐ Individual
times/week for weeks
☐ Petit Larceny Class
☐ 8 Hour Drug & Alcohol Education Class
☐ High School Equivalency/College Classes
☐ Trespassed From:
☐ No Contact With
☐ for case duration ☐ months
☐ Compliance with Conditions on Case(s)

☐ Jail sentence imposed. days
Suspended/Pending: days
Jail Time Served: days
Balance of Jail Due: days
Converted to: ☐ House Arrest ☐ Com. Svc
☐ House Arrest days
☐ Community Service hours;
(To be completed at a min. rate of 4 hrs/week)
☐ No Further Arrests or Criminal Cites
☐ Same/ Similar ☐ Any Criminal
☐ Duration ☐ months/years
☐ One year or duration-whichever is longer
☐ **No Possession / Use of Alcohol
☐ **No Possession / Use of Controlled Substances - including Marijuana, unless a Nevada medical marijuana card is obtained
Submit to testing as deemed necessary by SPS
☐ No Weapons ☐ Submit to search of person, residence, vehicle, or property under your control, as instructed by SPS
☐ Other:

☐ UNSUPERVISED / COURT ORDERED STATUS CHECKS

UNSUPERVISED PARTICIPANTS. You must provide the Court completion certificates/documentation for court ordered programs on or before your return court date. For a list of approved classes/programs please refer to http://cityofhenderson.com/alternative-sentencing

COURT DATES: ☐ None at this time ☐ Return Court Date: / / @ : AM / PM
Department 1 / 2 / 3 ☐ Appearance Required ☐ **Appearance Not Required if compliant with ALL orders**

It is hereby ordered this day of , 20 .

Presiding Judge of the Henderson Municipal Court

HENDERSON MUNICIPAL COURT: SENTENCING ORDER

CITY OF HENDERSON, Plaintiff
VS.
[illegible], Cristian Defendant

) Case #: _____
) DR #: _____
) ☐ DOMESTIC BATTERY / ☐ DUI:
) ☒ 1ST Offense / ☐ 2nd Offense
) ☐ OTHER (List Below): _____

☐ Guilty; ☐ Nolo; ☐ Adjudication Stayed ☐ Submitted on the Record,
Pending: ☐ Dismissal; ☐ Amendment to _____
Total Fines/AA Fees Imposed: $ _____ Fines/Fees Suspended if compliant: $ _____
☒ $35 DB Assessment Fee ☐ $60 Blood/Breath Test ☐ $50 Time Payment Setup Fee; ☐ $100 DUI Specialty Courts' Fee
Total Fines/Fees Due: $ _____ Payments: $ _____ per month or fine due in full by/beginning ____/____/____
Mail to: Henderson Municipal Court, PO Box 95050 - MS621, 243 Water Street, Henderson, NV 89009 On-line: www.cityofhenderson.com/municipal_court/

THE ABOVE REFERENCED DEFENDANT IS HEREBY SENTENCED TO THE FOLLOWING:

**********SENTENCING CONDITIONS**********

☐ **PROBATION / DIRECT SUPERVISION** (See Agreement & Rules Form) ☒ **PROBATION / INDIRECT SUPERVISION**

You must appear in person to Special Programs and Services (SPS), located at 243 Water Street, Lower Level, Henderson, NV immediately following court or upon the first business day following your release from custody. Failing to appear at the Special Programs and Services office, failing to comply with the court's order or receipt of a non-compliant report from any agency may result in immediate arrest for Probation Violation or a Bench Warrant issued for your arrest. You must report to Special Programs and Services as directed throughout the term of Supervision. You must provide correct contact information to Special Programs and Services and report any changes of that information immediately.

Probation / Supervision Expiration Date: ___/1__/____

☐ DUI School
☐ Victim's Impact Panel
☐ Coroner's DUI Program
☐ Breath Ignition Interlock Device **
☐ Suspension of Registered Vehicles **
** Separate order required
☐ SCRAM Program _____ weeks/months
☐ Install Prior to Release from Custody
☐ Report out-of-custody to SPS upon release for installation
☐ AA / NA / GA (or Acceptable Alternative)
☐ Sponsor required _____ x/wk for ____ wks
☐ DART Program
☐ _____ weeks/month ☐ Duration
☐ Controlled Subst. including Marijuana
☐ Alcohol
☐ CAT Program _____ weeks/months
☐ Coroner's Visitation Program (CVP)
☐ Restitution of $_____
Payable to City of Henderson on behalf of:
_____
☐ Via Monthly Payments $_____
☐ In Full by/beginning ____/____/____
(Submit payment to SPS)

☐ Domestic Battery Counseling (26 sessions, 1x/week)
☐ Long-Term Domestic Battery Counseling (52 sessions, 1x/week)
☐ Surrender, Sell or Transfer Firearms
** Separate order required
☐ Anger Control Management
☐ Level 1 ☐ Level 2
☐ Substance Abuse Counseling (SAC)
☐ Outpatient SAC ☐ Inpatient SAC
☐ Intensive outpatient SAC
☐ Group / ☐ Individual
_____ times/week for _____ weeks
☐ Petit Larceny Class
☐ 8 Hour Drug & Alcohol Education Class
☐ High School Equivalency/College Classes
☐ Trespassed From:
_____
☐ No Contact With :_____
☐ for case duration ☐ _____ months
_____
_____
☐ Compliance with Conditions on Case(s)
_____

☒ Jail sentence imposed: _____ days
Suspended/Pending: _____ days
Jail Time Served: _____ days
Balance of Jail Due: _____ days
Converted to: ☐ House Arrest ☐ Com. Sv
☐ House Arrest _____ days
☐ Community Service _____ hours;
(To be completed at a min. rate of 4 hrs/week
☒ No Further Arrests or Criminal Cites
☐ Same/ Similar ☒ Any Criminal
☐ Duration ☐ ____ months/years
☐ One year or duration-whichever is longe
☐ **No Possession / Use of Alcohol
☐ **No Possession / Use of Controlled Substances - including Marijuana, unless a Nevada medical marijuana card is obtained
**Submit to testing as deemed necessary by SPS
☐ No Weapons ☐ Submit to search of person, residence, vehicle, or property under your control, as instructed by SPS
☒ Other: _____
_____
_____

☐ **UNSUPERVISED / COURT ORDERED STATUS CHECKS**

UNSUPERVISED PARTICIPANTS: You must provide the Court completion certificates/documentation for court ordered programs on or before your return court date.
For a list of approved classes/programs please refer to https://www.cityofhenderson.com/special-programs-and-services

COURT DATES: ☒ **None at this time** ☐ **Return Court Date:** ____/____/____ @ ____:____ **AM / PM Department 1 / 2 / 3**
☐ **Appearance Required** ☐ **Appearance Not Required if compliant with ALL orders**

It is hereby ordered this _____ day of _____, 20____.

_____
Presiding Judge of the Henderson Municipal Court

Original-Court / Yellow= SPS/ Pink=Defendant (100119)

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy #206 – Reno, NV 89521

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE - PRESCRIBE

REGISTRATION FEE: FOR AUTHORITY TO PRESCRIBE DANGEROUS DRUGS ONLY $80.00 TOTAL
FOR AUTHORITY TO PRESCRIBE CONTROLLED SUBSTANCES $200.00 TOTAL

(Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

First: Aubree Middle: Megan Last: Teribury

Home Address: [redacted] Double R Blvd Apt [redacted]

City: Reno State: Nevada Zip Code: 89521

SS# or ITIN: [redacted] Date of Birth: [redacted] Sex: ☐ M or ☒ F

Telephone: [redacted] E-mail address: [redacted]

PRACTICING LOCATION (Required)

Practice Name (if any): Aesthetics Med Spa

Physical Address: 6295 Sharlands Ave Suite #: C1

City: Reno State: Nevada Zip Code: 89523

Telephone: 775-825-1586 Fax:

Nursing Board #: 816520 Issued: 01/27/2021 Expires: 12/05/2022

☐ **Check this box if you are an APRN who intends to apply for DEA Registration. Board Staff will notify DEA and you of the required information and provide a letter with your pending number to allow you to apply for the DEA in Nevada-(Do not apply to DEA before receiving your pending letter.) (Provide $200.00 Total Registration fee)**

You must have a current Nevada license with your respective BOARD before we will process this application. The Nevada license must remain current to keep the controlled substance registration.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☒
2. Been the subject of a board citation, administrative action whether completed or pending in any state?	☒	☐
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:
Public Reprimand	CA	12/23/2020	40020190004079

Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

It is a violation of Nevada law to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

I understand that Nevada law requires a licensed APRN who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Original Signature of APRN, no copies or stamps accepted — Date: 5/13/2021

COLLABORATING PHYSICIAN's name (If required):

Original Signature of Collaborating Physician, no copies or stamps accepted — Date

Board Use Only: Date Processed — Amount 80

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

Required Addendum for APN's and PA's applying for DEA registrations

Please complete the following information and return by mail to address above or by fax to (775) 850-1444. When the completed form has been received and is complete, we will notify DEA of the required information.

Name: Aubree Teribury (APN) or PA (Circle one)

Practicing Address: 950 Mill Street
(This can not be a home address)

City: Reno State: NV Zip: 89502

Telephone: [redacted]

Fax: ( )

Email: [redacted]

Supervising Physician: Dr. Michael Casal

Signature: [signature] Date: 6/15/2021

Board Use Only

Date Received: Date DEA notified:

Pending CS #: Lic #:

June15, 2021

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy #206

Reno, NV 89521

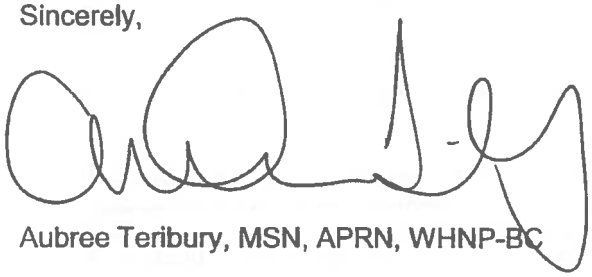
To Whom it May Concern,

I have attached an updated addendum for my Pharmacy Board application. Due to confusion regarding my area of practice within The Well Care Group Clinic the wrong collaborating physician was given to me.

The attached addendum has the correct collaborating physician, Dr. Michael Casal, OB-GYN who will oversee my practice as a Women's Health Nurse Practitioner in The Well Care Group Clinic.

Furthermore, this letter stands as my authorization for the $200 plus 5% credit card charge for my controlled substances license. The credit card authorization form was sent with my original application. Please advise if any further information is needed and I apologize for the confusion.

Sincerely,



Aubree Teribury, MSN, APRN, WHNP-BC

Nevada State Board of NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

Aubree Teribury

Wednesday, June 02 2021 11:24:06 AM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
Teribury, Aubree	RN	816520	Inactive	12/11/2018	01/15/2019	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
Teribury, Aubree	RN	816520	Active	01/15/2019	12/05/2022	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
Teribury, Aubree	APRN-CNP	816520	Active - Prescribing	01/27/2021	12/05/2022	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Women's Health / Gender Related
  - Has discipline: NO
  - Expiration Date: 12/05/2022
  - Original Issuance Date: 01/27/2021
  - Current Issue Date: 01/27/2021
  - Certification expiration date: 12/15/2023

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

May 11, 2021

Nevada State Board of Pharmacy

985 Damonte Ranch Pkwy #206

Reno, NV 89521

To Whom it May Concern,

I am attaching a copy of the letter and mitigating evidence I sent to the NSBN explaining the public reprimand I received on December 23, 2020 relating to case # 4002019004079 on my California Registered Nursing License # 95164504. My case with the NSBN was closed with no discipline and my NSBN Registered Nursing License was fully renewed and I was awarded an Advance Practice Nursing License with Prescribing Privileges.

If you would like any further explanation, please advise.

Sincerely,

Aubree Teribury, MSN, APRN, WHNP-BC

CRAIG K. PERRY & ASSOCIATES
3450 W. CHEYENNE AVE., SUITE 400 • NORTH LAS VEGAS, NEVADA 89032
(702) 228-4777 PHONE • (702) 943-7520 FAX

November 12, 2020

VIA EMAIL ONLY
folmstead@nsbn.state.nv.us

Fredrick R. Olmstead, Esq.
Nevada State Board of Nursing
5011 Meadowood Mall Way, Suite 300
Reno, Nevada 89502-6567

RE: Our Client: Aubree Teribury

Dear Mr. Olmstead:

Please be advised that this law firm has been retained to represent the interests of the above-referenced client.

Ms. Teribury is preparing to renew her license on or before December 5, 2020 in the State of Nevada. She is also licensed in California as of 5/21/2018. Prior to that, she obtained her first license in Georgia in 2014.

On or about May 4, 2020, formal accusations were filed against Ms. Teribury in California, where she worked as a travel nurse (her second assignment). On October 22, 2020, she signed a Stipulated Settlement and Disciplinary Order for Public Approval. In it, she stipulates that she admits the facts set forth in the Accusation. Both the Accusation (i.e., Complaint) and the Stipulation are provided hereto.

Here's the short version of what occurred: on November 22, 2018, Ms. Teribury was working as a registered nurse, and gave 1.8 units (ml) of insulin to a patient instead of .18 (ml). She did not use an "insulin syringe" at the time. Additionally, she had previously, successfully used the 1 ml syringes to administer insulin at other hospitals.

In mitigation of this error, there are three things to consider:

1. Ms. Teribury is a relatively new nurse at this facility and had been working there of approximately 9 weeks of a 13-week contract. She had received three days of orientation when she began

2. This incident was the first time that my client had administered insulin at the facility. Insulin syringes were kept in a separate drawer, away from all other syringes. She was not made aware of this; also, in the past, she had confidently and correctly used the 1 ml syringes to administer insulin at other hospitals. Because the facility was very busy on her shift, there was no one available to ask if they had any insulin syringes or where they were.

3. Before administering the insulin injection, she requested that her charge nurse, referred to as "S.L.," verify the amount of insulin that she was about to administer. My client showed the charge nurse both the bottle and both (1 ml) syringes, which were in the plain view of the charge nurse, Next, the charge nurse signed the patient's medical record indicating that she had verified the 1.8 ML as being the correct amount to administer;

4. Ms. Teribury took responsibility, and readily admitted to the error once it was discovered;

5. She continued to work for this facility for 3.5 weeks without any errors;

5. Exhibits A through N, which include the following:

A. Evidence of a Master's degree in nursing;

B. Ms. Teribury's résumé

C. Her transcripts from school demonstrating her excellence as a student

D. A work appraisal form Carson Tahoe Health, June 3, 2019, which positively assessed both her competence and functionality as a nurse;

E.-M. Letters of reference concerning Ms. Teribury; and

N. A list of coursework that she has completed as a nurse.

As a result of this error, Ms. Teribury is in the process of being disciplined by the Board of Registered Nursing, Department of Consumer Affairs, State of California. Specifically, she is being required to do the following:

(a) Complete recommended course work in the next six months; and

(b) Pay a hefty fee for the costs associated with the investigation ($6,778.46).

Attached you will find (1) A statement from my client, (2) a copy of the Accusation, which contains the facts I've repeated here that were stipulated to by my client; and (3) a copy of the Stipulated Settlement and Disciplinary Order.

The Order has yet to be signed off in the State of California. My suggestion is that the Nevada Board wait and make sure the Decision and Order is approved and signed by the Board of Registered Nursing before deciding how to act on this matter.

Very truly yours,

CRAIG K. PERRY & ASSOCIATES

CRAIG K. PERRY, Esq.
CKP/tk

Enclosures: as stated above

Statement of Aubree Teribury

My name is Aubree Teribury. I have reviewed the facts set forth in the Letter of Representation prepared by my attorney, Craig K. Perry. The facts set forth therein are true and correct to the best of my knowledge.

I would like to tell you a little about myself and my commitment to the practice of nursing, as well as explain what occurred on November 22, 2018.

I am a Registered Nurse in the State of Nevada whose license is coming up for renewal. I recently obtained my Master's Degree in Nursing in 2020 in order to become a Nurse Practitioner, with an emphasis in Women's Health. I have passed the Boards and have applied to the Nursing Board for licensure to practice as a nurse practitioner in this State. The Board already has a copy of my transcripts and test results.

I began my career in nursing in my home state of Georgia in 2014. Later, I became licensed in California in 2018, where I worked as a traveling nurses for various medical providers. Those are listed on my résumé, which I am providing with this statement and my attorney's letter.

The second assignment that I received as a travel nurse in California from my agency was at the Sierra Vista Regional Medical Center ("SVRMC"). I was contracted to work there for 13 weeks. When I began, I received three days of orientation before I began

About nine weeks into my contract, on November 22, 2018, I was supposed to give a patient .18 units (ml) of insulin. However, I thought the order stated 1.8 units. This was a serious error on my part for which I have taken full responsibility. Nothing like this has ever happened before or since this incident.

This was the first time at SVRMC that I had to give an insulin shot to any patient. In other facilities where I had worked, some facilities had insulin syringes, and some did not. I have confidently and correctly used larger syringes to administer insulin on patients prior to this occasion.

Because I was using 1 ml syringes, I needed to use two of them. I did not ask about the availability of the smaller, insulin syringes because everyone was busy during this particular shift, and there was no one available to ask. Additionally, I didn't know whether or where the facility kept the smaller syringes, because they were not in the drawer with the other sized syringes. Afterwards, I learned that these insulin syringes were kept in a separate drawer.

Before administering the insulin, I did consult with the Charge Nurse ("S.L."), who read the doctor's prescription the same way I did, approved the dosage, and signed off on the patient's medical record. In addition, the two syringes that I was going to use were in the plain view of S.L., because I showed them to her.

It was not until later, when a family member asked why there were two syringes, that we caught the error. I immediately acknowledged my error, and I am grateful that the patient was not harmed from this incident. I continued working at this facility, until my contract ended approximately 3 and a half weeks later, without incident.

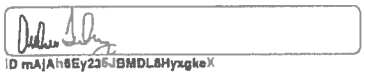
///

///

As a result of this incident, I agreed to be disciplined by the Nursing Board in California, for which I paid the costs of the proceeding (nearly $7,000) and will be taking continuing education classes, in addition to receiving a public reprimand.

I've provided to my attorney my school transcripts, degree information, recent evaluations and statements of various people who are aware of the quality of my work and my commitment to the nursing profession.

Date: 11/11/2020



Aubree Teribury

eSignature Details

Signer ID:	**mAjAh6Ey235JBMDL8HyxgkeX**
Signed by:	Aubree Terlbury
Sent to email:	[redacted]
IP Address:	
Signed at:	Nov 12 2020, 3:24 pm PST

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
BOARD OF REGISTERED NURSING
PO Box 944210, Sacramento, CA 94244-2100
P (916) 322-3350 F (916) 574-8637 | www.rn.ca.gov

January 20, 2021

AUBREE MEGAN TERIBURY
[redacted] GAP CREEK TER
NEWBORN, GA 30056-3206

Re: Case No. 4002019004079

Dear AUBREE MEGAN TERIBURY:

This letter serves as acknowledgement of receipt of payment in the sum of $6,778.46. The fine amount required by case number 4002019004079 is paid in full.[1]

Please feel free to contact the Board of Registered Nursing if you have any questions regarding this matter.

Sincerely,

Legal Support Unit
Enforcement Division
Board of Registered Nursing
BRNfines@dca.ca.gov

400.CITE8.042219

[1]A check that cannot be processed due to insufficient funds will result in your case being re-opened. Your license will also be deemed non-renewable until payment is received.

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
BOARD OF REGISTERED NURSING
PO Box 944210, Sacramento, CA 94244-2100
P (916) 322-3350 F (916) 574-8637 | www.rn.ca.gov

January 21, 2021

Aubree Megan Teribury
[redacted] Gap Creek Ter
Newborn, GA 30056-3206

Re: Required Coursework for Case No. 4002019004079

Dear Aubree Megan Teribury:

As stipulated by your public reproval, you were required to complete coursework as assigned by the Board of Registered Nursing. **This letter acknowledges the receipt of your documentation and is to inform you that you have successfully completed the coursework that was required of you.**

NCSBN Course?	Course Name/Type	Required No. of Hours	Status
☒ Yes ☐ No	Professional Accountability & Legal Liability	N/A	COMPLETE
☒ Yes ☐ No	Righting a Wrong: Ethics and Professionalism in Nursing	N/A	COMPLETE
☒ Yes ☐ No	Sharpening Critical Thinking Skills	N/A	COMPLETE
☒ Yes ☐ No	Medication Errors: Causes & Prevention	N/A	COMPLETE
☐ Yes ☒ No	Nursing Practice: Nursing management of insulin including appropriate equipment and calculation of dosage	9	COMPLETE

This letter should be maintained for your records.

Sincerely,

Board of Registered Nursing

October 19, 2020

UPLOADED ELECTRONICALLY

Re: Renewal of Licensure for Aubree Teribury

Attached please find the following documents in support of Aubree Teribury:

Exhibit	A.	Master's degree in nursing Aubree Teribury
Exhibit	B.	Resume of Aubree Teribury
Exhibit	C.	Aubree Teribury Transcripts
Exhibit	D.	Carson Tahoe Health Work Appraisal
Exhibit	E.	Renown Labor and Delivery Annual Evaluation
Exhibit	F.	Continuing Education Certificates
Exhibit	G.	Alison Taylor Letter of Reference
Exhibit	H.	Kathryn Rasor Letter of Reference
Exhibit	I.	Laura Morgan Character Reference
Exhibit	J.	Ree A. Standiford Letter of Reference
Exhibit	K.	Lora Carlson Letter of Reference
Exhibit	L.	Melissa Lawrence Letter of Reference
Exhibit	M.	Sharon Bonifazi Letter of Reference
Exhibit	N.	Nurse Practitioner Coursework

EXHIBIT "A"

UAB SCHOOL OF NURSING

August 19, 2020

National Certification Corporation
142 E. Ontario Street
Suite 1700
Chicago, IL 60611

Dear Madam/Sir:

This letter is to confirm that on September 4, 2020, Aubree Teribury was awarded a Master's Degree in Nursing with a concentration of Women's Health Nurse Practitioner at the University of Alabama at Birmingham. This student's diploma will arrive within the next 8 to 12 weeks. In the meanwhile, please use this letter as proof of graduation.

If you have any questions regarding this student's academic status or graduation, please contact me at 205-996-4509.

Sincerely,

Bryan Combs, PhD, CRNP, FNP-BC, CNL, ATC
Nurse Practitioner Pathway Director
School of Nursing
UAB | The University of Alabama at Birmingham
NB 446 | 1701 University Blvd. | Birmingham, AL 35294-1210
P: 205.996.4509 | M: 205.901.7932 | F: 205.996.7177 | bryancombs@uab.edu

EXHIBIT "B"

Aubree Teribury
[redacted] Double R Boulevard, Apt [redacted], Reno, NV 89521 · [redacted] · [redacted]

Objective

Board Certified Women's Health Nurse Practitioner with clinical experience in uncomplicated, preventative, and complex OB/GYN and primary women's health care seeking a position that enables me to utilize my skills and offers the opportunity for professional growth and development.

Qualifications

- Ability to work independently with minimal supervision in a fast-paced environment
- Exemplary nursing and patient management skills
- Excellent collaborative and communication skills

Education

Master of Science Nursing- WHNP 2018-2020
University of Alabama at Birmingham, Birmingham, AL
Accredited University, School of Nursing

Bachelor of Science Nursing 2009-2014
University of West Georgia, Carrollton, GA
Accredited University, School of Nursing
April 2014 *Deans List* GPA: Nursing: 3.55 Overall: 3.28/4.0

Related Coursework

- Skills Assessment
- Clinical Skills Practice
- Pharmacology, Healthcare across the life span, professional nursing concepts

WHNP Clinical Rotations

Fall 2019 *OBGYN Associates- Reno, NV (180 hrs)*
Spring 2020 *Renown Women's Health/Renown Women's Ryland- Reno, NV (130.5 hrs)*
Summer 2020 *Renown Women's Health/Renown Women's Ryland- Reno, NV & Carson Medical group- Carson City, NV (188 hrs)*

Activities

Chi Omega 2009-2013, *Executive Council* 2012-2013

- Treasurer
  - Managing chapter funds, collecting of funds and payment of bills and fees
  - Make-a-Wish, *Georgia*
    - Aided in the granting of a $5,000 wish
    - Participated and organized fundraisers

Employment History

University of Nevada Reno
1664 N Virginia St Reno, NV 89557 (775) 784-6841 — January 2021 – Present

- Orvis School of Nursing Clinical Faculty

Tahoe Forest Health District
10121 Pine Ave Truckee, CA 96160 (775) 982-4100 — December 2020 – Present

- Staff RN Temporary Part-Time (Women's and Family)

Aubree Teribury
[redacted] Double R Boulevard, Apt [redacted], Reno, NV 89521 · [redacted] · [redacted]

Renown Regional Medical Center
1155 Mill St Reno, NV 89502 (775) 982-4100 January 2019 – Present
- Staff RN Jan-Sept 2019/ Per Diem- Present (Labor and Delivery)
- Interim Educator- Feb 2021- Present

Carson Tahoe Regional Medical Center
1600 Medical Parkway Carson City, NV 89703 (775) 445-8000 June 2019 – February 2021
- Per Diem RN (Labor and Delivery)

Aya Healthcare
5930 Cornerstone Ct W San Diego, CA 92121 (866) 687-7390 June 2018 – December 2018
- Travel/Agency RN (Labor and Delivery)

Wellstar Kennestone Hospital
677 Church Street Marietta, Georgia 30060 (770) 793-5000 July 2017 – June 2018
- Staff RN II (Labor and Delivery)

Maxium Healthcare
2250 N Druid Hills Road NE Unit 275 Atlanta, Georgia 30329 (404) 325-5335 Jan 2017 – Dec 2017
- Travel/Agency RN (Labor and Delivery)

St. Josephs/ Candler Hospital
5353 Reynolds Street Savannah, Georgia 31405 (912) 819-8200 April 2015 – July 2017
- Staff RN (Labor and Delivery)

Memorial Health University Medical Center
4700 Waters Avenue Savannah, Georgia 31405 (912) 350-8000 July 2014-April 2015
- Staff RN 1 (Operating Room)

Additional Skills and Certifications

- Superior in medical histories, physical exams, laboratory testing, and medical prescriptions
- Exceptional patient care
- Certified in BLS for Healthcare Providers
- Certified in ACLS
- Certified in NRP
- AORN certificate in Peri-op Nursing
- Certificate in STABLE
- Certificate in Intermediate and Advanced Fetal Monitoring
- Trained in IUD placement

Academic Transcript

B01479634 Aubree Teribury
May 21, 2020 04:43 pm

This is not an official transcript. Courses which are in progress may also be included on this transcript.

Institution Credit Transcript Totals Courses in Progress

Transcript Data

STUDENT INFORMATION

Name : Aubree Teribury
Birth Date: [redacted]
Student Type: Continuing

Curriculum Information

Current Program
MS in Nursing
Program: MSN in Nursing
College: Nursing
Major and Department: Nursing, Nursing
Major Concentration: Women's Health Nurse Pract

This is NOT an Official Transcript

DEGREE AWARDED

Sought: MS in Nursing Degree Date:

Curriculum Information

Primary Degree
Program: MSN in Nursing
College: Nursing
Major: Nursing
Major Concentration: Women's Health Nurse Pract

INSTITUTION CREDIT -Top-

Term: Fall Term 2018
Academic Standing: Good Standing

Subject	Course	Level	Title	Grade	Credit Hours	Quality Points	R
NUR	604	GR	Ldrship in Adv Nur Prac Roles	A	3.000	12.00	
NUR	612	GR	Advanced Pathophysiology	B --	3.000	9.00	

Term Totals (Graduate)

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Current Term:	6.000	6.000	6.000	6.000	21.00	3.50
Cumulative:	6.000	6.000	6.000	6.000	21.00	3.50

Unofficial Transcript

Term: Spring Term 2019
Academic Standing: Good Standing

Subject	Course	Level	Title	Grade	Credit Hours	Quality Points	R
NUR	605	GR	Translating Evidence into Prac	A	3.000	12.00	
NUR	613	GR	Pharmacology and Therapeutics	B	3.000	9.00	

Term Totals (Graduate)

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Current Term:	6.000	6.000	6.000	6.000	21.00	3.50
Cumulative:	12.000	12.000	12.000	12.000	42.00	3.50

Unofficial Transcript

Term: Summer Term 2019
Academic Standing: Good Standing

Subject	Course	Level	Title	Grade	Credit Hours	Quality Points	R
NUR	610	GR	Hlth Care Sys for Adv Nur Prac	A	3.000	12.00	
NUR	614	GR	Assess Diag Reasoning APN Prac	A	3.000	12.00	
NWH	618L	GR	Focus Adv Nur Prac Specializat	P	3.000	0.00	

Term Totals (Graduate)

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Current Term:	9.000	9.000	9.000	6.000	24.00	4.00
Cumulative:	21.000	21.000	21.000	18.000	66.00	3.66

Unofficial Transcript

Term: Fall Term 2019
Academic Standing: Good Standing

Subject	Course	Level	Title	Grade	Credit Hours	Quality Points	R
NWH	631	GR	Women's Health Adv Nur Pract I	A	5.000	20.00	
NWH	685L	GR	Pract I: Women's Hlth Care NP	P	3.000	0.00	

Term Totals (Graduate)

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Current Term:	8.000	8.000	8.000	5.000	20.00	4.00
Cumulative:	29.000	29.000	29.000	23.000	86.00	3.73

Unofficial Transcript

Term: Spring Term 2020
Academic Standing: Good Standing

Subject	Course	Level	Title	Grade	Credit Hours	Quality Points	R
NWH	632	GR	Women's Health Advanced NP II	A	4.000	16.00	
NWH	686L	GR	Pract II: Women's Hlth Care NP	P	3.000	0.00	

Term Totals (Graduate)

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Current Term:	7.000	7.000	7.000	4.000	16.00	4.00
Cumulative:	36.000	36.000	36.000	27.000	102.00	3.77

Unofficial Transcript

TRANSCRIPT TOTALS (GRADUATE) -Top-

Level Comments: Univ West Georgia-BSN April 2014

	Attempt Hours	Passed Hours	Earned Hours	GPA Hours	Quality Points	GPA
Total Institution:	36.000	36.000	36.000	27.000	102.00	3.77
Total Transfer:	0.000	0.000	0.000	0.000	0.00	0.00
Overall:	36.000	36.000	36.000	27.000	102.00	3.77

Unofficial Transcript

--COURSES IN PROGRESS -Top-

Term: Summer Term 2020

Subject	Course	Level	Title	Credit Hours
NWH	633	GR	Women's Health Adv Prac III	5.000
NWH	692L	GR	Resid. Women's Health Care NP	4.000

Unofficial Transcript

RELEASE: 8.7.1

EXHIBIT "D"

CARSON TAHOE HEALTH

Carson Tahoe Health System

Introductory Appraisal

90 day review**

First Name	AUBREE
Last Name	TERIBURY
Position Name	REGISTERED NURSE PER DIEM
Department Name	WOMEN'S & CHILDREN SERVICES
Facility Name	Carson Tahoe Regional Healthcare
Manager Name	SHELLY L KOONTZ
Hire Date	06/03/2019
Start Date	06/03/2019
FLSA status	N/A
Grade	38C
Classification Code	N/A

Values/Behaviors

Section Score: 5
Section Average: 1.00

Inspires Hope
(•) Yes ( ) No — Score: 1

- Conducts self with the highest ethical and moral standards
- Communicates respectfully; listening, seeking clarification, confirming understanding and providing feedback and avoiding gossip and destructive communication.
- Values individual differences including culture, race, national origin, age, gender, religion, political affiliation, veteran status, disability status sexual orientation and gender identity.
- Uses courtesy to convey respect for others, addressing others professionally, allowing others to step onto the elevator, escorting visitors to their destination.

Builds Trust
(•) Yes ( ) No — Score: 1

- Adheres to an appropriate and effective set of core values and beliefs during both good times and bad.
- Acts in line with those values and practice what he/she preaches
- Is widely trusted
- Is seen as a direct truthful individual
- Can present the truth in an appropriate and helpful manner
- Keeps confidences, admit mistakes, and doesn't misrepresent self for personal gain.

Is Compassionate
(•) Yes ( ) No — Score: 1

- Genuinely cares about people
- Concerned about work and non-work problems
- Readily available to help and assist in any way possible.
- Is sympathetic to the plight of others not as fortunate
- Demonstrates real empathy with the joys and pains of others.

Seeks Excellence
(•) Yes ( ) No — Score: 1

- Keeps the patient at the center of all improvements to our organization
- Seeks to understand conflicting opinions and perspectives
- Brings concerns to those who can resolve them
- Implements a newly made decision to the best of their ability
- Seeks input from others to test and improve ideas
- Responsible to bring a positive and helpful attitude to work

Contributes to Patient Centered Care
(•) Yes ( ) No — Score: 1

- Understands their job is essential to our mission to provide compassionate care without compromise.
- Seek first to understand people and then to be understood
- Generous with expertise, willingly sharing knowledge with patients, their families and friends
- Is empathetic to the fears and concerns of patient and employees and responds with empathy, expertise and expediency.

- Involves employees as an active participant in exploring ways that patient care can be delivered honoring their expertise and knowledge.

Essential Functions

Section Score: 6
Section Average: 1.00

Action Oriented/ Drives for Results: Enjoys working hard; is action oriented and full of energy for the things he/she sees as challenging; not fearful of acting with a minimum of planning; seizes more opportunities than others; can be counted on to exceed goals successfully; is constantly and consistently one of the top performers; very bottom line oriented; steadfastly pushes self and others for results.
(•) Yes ( ) No — Score: 1

Customer Focus: Is dedicated to meeting the expectations and the requirements internal and external customers; gets first-hand customer information and uses it for improvements in products and services; acts with customers in mind; establishes and maintains effective relationships with customers and gains their trust and respect.
(•) Yes ( ) No — Score: 1

Interpersonal Savvy: Relates well to all kinds of people, up, down, and sideways, inside and outside the organization; builds appropriate rapport; builds constructive and effective relationships; uses diplomacy and tact; can diffuse even high tension situations comfortably; can find common ground and solve problems for the good of all; can represent his/her own interests and yet be fair to other groups; can solve problems with peers with a minimum of noise; is seen as a team player and is cooperative; easily gains the trust and support of others; encourages collaboration.
(•) Yes ( ) No — Score: 1

Teamwork: Creates strong morale and spirit within his/her team and across other parts of the organization; shares wins and successes; fosters open dialogue; helps create a feeling of belonging to the team; builds rapport well, is a good listener; is sensitive to and patient with the interpersonal anxieties of others.
(•) Yes ( ) No — Score: 1

Safety: Contributes to a safe work environment; is attentive to the safety of fellow employees and of patients, by demonstrating safe work habits; follows all safety guidelines for given roles, and encourages others to do the same, reports unsafe work practices, uses occurrence and service recovery system.
(•) Yes ( ) No — Score: 1

Functional/ Technical Skills: Possesses in-depth technical knowledge; understands job procedures, policies, responsibilities; keeps up-to-date technically; acts as a resource person on whom others rely on for assistance; has the functional and technical knowledge and skills to do the job at a high level of accomplishment; uses his/her time effectively and efficiently; values time; concentrates his/her efforts on the more important priorities; gets more done in less time than others; can attend to a broader range of activities.
(•) Yes ( ) No — Score: 1

1. Completion of new hire Company On-line Training (RELIAS):
   (•) Yes ( ) No — Score: N/A
2. Acknowledgement of requirement to follow code of conduct obligations:
   (•) Yes ( ) No — Score: N/A
3. Acknowledgement of requirement to follow company policies and procedures:
   (•) Yes ( ) No — Score: N/A

Completion of Probation Period

1. Did the employee score 3 or more "Yes" for Values/Behavior? (If not, select No for Completion of Probationary Period):
   (•) Yes ( ) No — Score: N/A
2. Did the employee score 3 or more "Yes" for Essential Functions? (If not, select No for completion of Probationary Period):
   (•) Yes ( ) No — Score: N/A

Completion of Probation Period:
(•) Yes ( ) No — Score: N/A

Total Score: 11
Total Possible Score: 11

Manager Comments

Aubree has been a great addition to the OB team. S

Signature History

Comment	Signature Value	Created Date	Employee Full Name
	SHELLY L KOONTZ	10/04/2019	KOONTZ, SHELLY L
	AUBREE M TERIBURY	10/12/2019	TERIBURY, AUBREE M

EXHIBIT "E"

Renown HEALTH — Inside Renown

± Evaluation - Staff : Teribury, Aubree : Annual Evaluation

I. Living Our Values | II. Performance Summary – Values | III. Performance Summary - Job | IV. Requirements | V. Development Plan | VI. Comments | VII. Signatures

< Previous Section | Caring | Integrity | Collaboration | Excellence | Next Section >

Expectations

Caring: We are caring and compassionate.

- Welcome
  - Use the 10-5 rule
  - Welcome guests by the name they prefer, affirm they are in the right place
  - Listen to understand others' perspective
  - Give others your full attention
- Connect with Compassion
  - Reassure guests we will take very good care of them
  - Stay off cell phones and laptops while in meetings and "on-stage" areas
  - Encourage team members and show confidence in them
  - Manage relationships effectively due to good sense of self-awareness

< Previous Section | Next Section > | Save Eval | Open as PDF | Logout

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

I. Living Our Values

The Values are the specific behaviors we will exhibit as we go about achieving our Mission.. For each Value, assess based on the descriptions of each rating and the Methods of Assessment found on the last page of this form.

Expectations	Rating	Method of Assessment	Example
Caring: We are caring and compassionate.			
-Welcome -Use the 10-5 rule -Welcome guests by the name they prefer, affirm they are in the right place -Listen to understand others' perspective -Give others your full attention -Connect with Compassion -Reassure guests we will take very good care of them -Stay off cell phones and laptops while in meetings and "on-stage" areas -Encourage team members and show confidence in them -Manage relationships effectively due to good sense of self-awareness	3 - Exceeds Expectations	Observed Data Demonstrated	Aubree provides her full attention to her patients. She stays focused on her patient care and listens carefully to their concerns and needs.
Integrity: We demonstrate respect and integrity.			
-Respond with Respect -Explain information so others understand the next step in their process and how long it will take -Own problems, take responsibility and resolve issues -Maintain confidentiality and considered trustworthy -Make decisions that support our Mission and Vision -Understand measures of department success	2 - Meets Expectations	Observed Data Demonstrated	Aubree is up-to-date on current standards and full of knowledge. She answers all of her patients questions fully and provides good explanation.

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

I. Living Our Values

The Values are the specific behaviors we will exhibit as we go about achieving our Mission.. For each Value, assess based on the descriptions of each rating and the Methods of Assessment found on the last page of this form.

Expectations	Rating	Method of Assessment	Example
Collaboration: We collaborate with our patients, families, employees, partners and communities.			
-Anticipate Needs -Use purposeful rounding with guests -Provide comfort and resources before being asked -Escort others to their destination -Communicate clearly and share information, knowledge and expertise -Take the initiative to help others -Actively engage in the department and/or department/organizational committees	2 - Meets Expectations	Observed Data Demonstrated	Aubree takes her patients needs and concerns into consideration when taking care of them. She is a great patient advocate. Aubree shares up-to-date information and previous experiences with other staff members.
Excellence: We strive for excellence in all we do.			
-Ensure Excellence -Speak positively about employees who precede and follow me in the continuum of care -Conclude every interaction with sincere thanks and appreciation -Use peer to peer guidance to support a culture of excellence -Focus on quality and safety by stopping the line and adhering to Renown Health policies and procedures -Motivated to gain knowledge and learn new skills -Utilize Transformational Health Care to improve processes and eliminate inefficiencies	3 - Exceeds Expectations	Observed Data Demonstrated	Aubree does not participate in negativity or gossip in the unit. She continually stays focused on her patients and the care she provides. She is currently in schoo and eager to learn and advan e with in her career.

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

II. PERFORMANCE SUMMARY – Living Our Values

	Rating
Caring	3
Integrity	2
Collaboration	2
Excellence	3
Total	10
Divide total By 4	2.5

III. PERFORMANCE SUMMARY - JOB-SPECIFIC DUTIES AND RESPONSIBILITIES

Instructions: For each job-specific duty or responsibility listed in the Position Description, assess based on the descriptions of each rating found on the last page of this form. Transfer scores to table below AND attach a copy of Position Description.

Duties and Responsibilities (transfer from current position description)	Weight		Score		Total Points Weight X Score	Method of Assessment
Living Our Values	30%	X	2.5	=	75	
Management of Patients	15%	X	2.25	=	33.8	Observed Data Demonstrated
Clinical Competency	15%	X	2.25	=	33.8	Observed Data Demonstrated
Professional Standards	20%	X	2.33	=	46.6	Observed Data Demonstrated
Customer Satisfaction	10%	X	2	=	20	Observed Data Demonstrated
Quality Programs	10%	X	0.8	=	8	Observed Data Demonstrated
Total	100%				217.2	

Attached Position Description: ATeriburyJobDesc2020.pdf

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

IV. REQUIREMENTS

Competencies	Status	Comments
1. License verification (attach copy of license and primary source verification from issuer) License #: 815520 State: Exp. Date: 12/5/2020 Description: RN	Completed	
2. Certification verification (all certifications required by position description including BLS, ACLS, specialty certifications, etc.) Certification #: Exp. Date: 7/31/2020 Description: BLS Certification #: Exp. Date: 9/30/2021 Description: NRP Attached: NRP EXP 09.2021.pdf Certification #: Exp. Date: 4/30/2020 Description: ACLS Certification #: Exp. Date: 2/29/2020 Description: STABLE	Completed	
3. Initial Competencies, OSHA and other required Online Learning Modules completed by due dates (print and attach OLA transcript)	Completed	
4. Department specific and job specific competencies completed (attach introductory or annual competency list)	N/A	
5. Clinical evaluation Due Date: 1/21/2020		
6. Mock code or other evaluation Due Date: 1/21/2020	Completed	
7. Total Compensation Package review - brief summary of compensation (print sheet from Total Compensation Package)	Completed	
8. PACE Program	Level 1: N/A Level 2: N/A Level 3: N/A Level 4: N/A Level 5: N/A	

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id	40375
Department:	Labor And Delivery S2	Dept. ID	200206
Review Date:	1/21/2020	Position Description Rev. Date	1/10/2020
Position Title:	Registered Nurse	Job Code	640102

IV. REQUIREMENTS

Course Name	Date Completed	Certificate
Committees		
Committee Attending		**Position Held**
Professional Organizations		
Professional Organization		**Offices Held**
Nurse Practitioner Women's Health		member
Community Benefit		

Staff Evaluation - Annual Evaluation

Employee Name:	Tenbury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

V. DEVELOPMENT PLAN

All employees, regardless of the overall score, must have a Development Plan. The Development Plan must specifically address any standard or job specific duty or responsibility that is scored (1) "Needs Development" or (0) "Unsatisfactory" with clear steps that will be taken to improve the performance level. You may attach additional documentation for this purpose. Please review the results from the previous pages and complete the following:

Maximize current strengths by focusing on and continuing to (at least three):

1. Determination, accomplishing goals
2. Honest and accountable for actions
3. Organization

Increase effectiveness by starting or stopping the following (at least three):

1. Time management
2. Focus on facts and not over analyze
3. Increase engagement and involvement

Development Goals (at least one):

1. Seek opportunities for growth within specialty

Progress check at 90 days 4/9/2020 180 days 7/8/2020

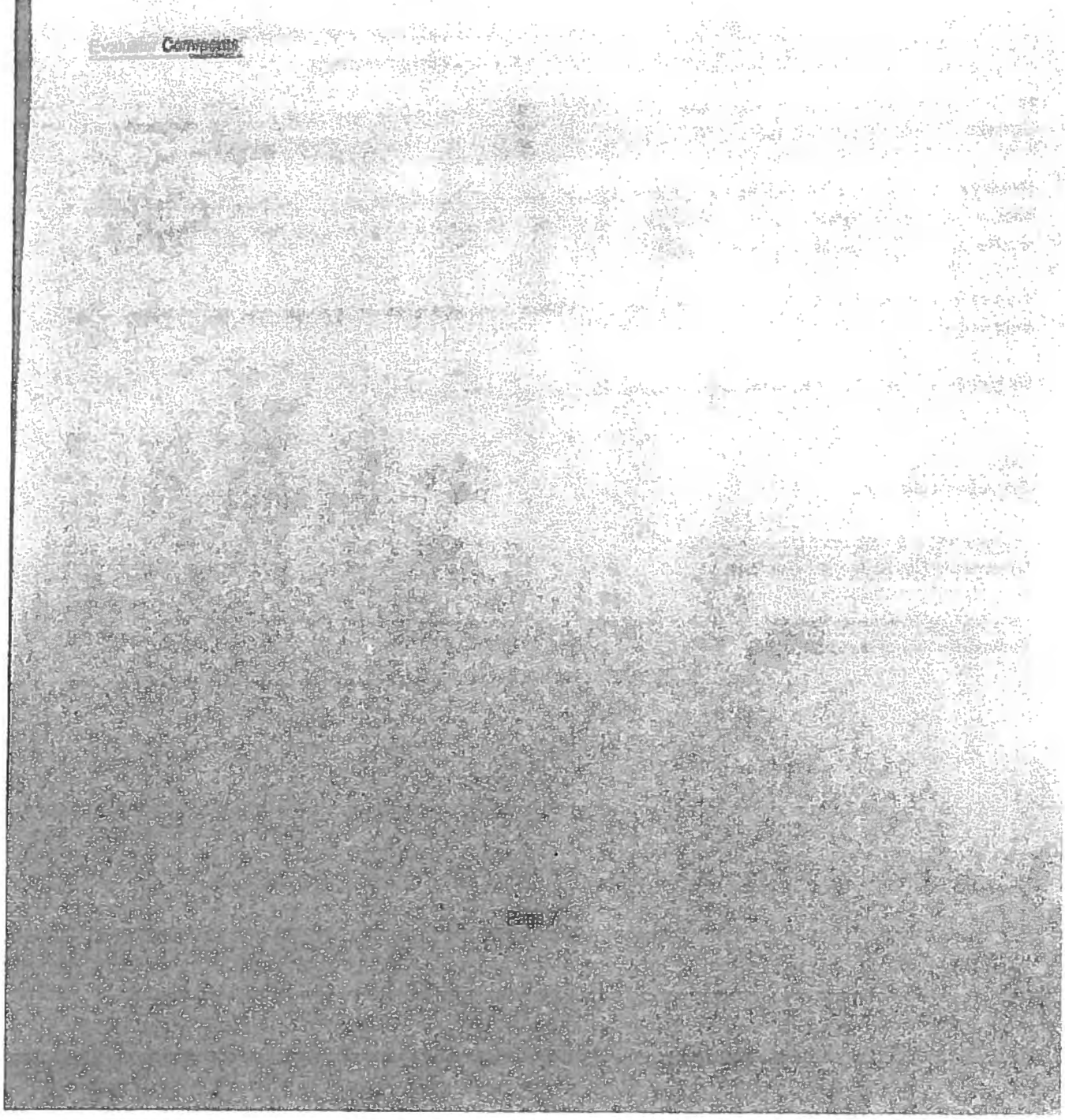
Staff Evaluation - Annual Evaluation

Employee Name:	Tenbury, Aubree	Employee ID	40375
Department:	Labor And Delivery 32	Dept ID	200206
Review Date:	1/21/2020	Position Description Rev. Date	1/10/2020
Position Title:	Registered Nurse	Job Code	640102

VI. COMMENTS

Employee Comments:

Evaluation Comments:



Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

VII. SIGNATURES

ACKNOWLEDGEMENT

I acknowledge that my leader thoroughly reviewed my performance for the performance period, created a meaningful development plan, and reviewed my total compensation package in a comprehensive manner.

I further acknowledge that I have read and understand the position description delivered at this evaluation. I have reviewed all performance standards and understand that these standards will be used as criteria for evaluating my performance.

I hereby acknowledge that I currently hold, or will obtain within the amount of time specified, all required licensure and certifications listed in the minimum requirements section of the position description. I understand that it is my responsibility to maintain the required licensure and certifications (as applicable).

It is further understood that the position description may be modified at any time to reflect changes necessary in departmental and/or organizational needs.

My typed name below shall have the same force and effect as my written signature.

Aubree Teribury	1/13/2020
Employee's Signature	Date
Kimberly Nevin Supervisor of Clinical Nursing	1/10/2020
Evaluator's Signature and Credentials	Date
Lois Carlson, Manager of Nursing	1/10/2020
Evaluator's Supervisor's Signature	Date

Staff Evaluation - Annual Evaluation

Employee Name:	Teribury, Aubree	Employee Id:	40375
Department:	Labor And Delivery S2	Dept. ID:	200206
Review Date:	1/21/2020	Position Description Rev. Date:	1/10/2020
Position Title:	Registered Nurse	Job Code:	640102

Attachments

Attachments can be found under the PDF Navigation Pane along the left hand side. If the Navigation Pane is not viewable right click on this document and select the option to "Show Navigation Pane Buttons"

Below is the list of attachments in the document.

Position Description:	ATeriburyJobDescrip2020.pdf
Certifications:	NRP EXP 09-2021.pdf
Department/Job Compentencies:	2020 Evaluation Teribury.pdf

EXHIBIT "F"

Nurse CE4less

NurseCe4Less.com
Certificate of Completion

Aubree Teribury

License number: 95164504

Is awarded 2.0 online Contact Hours
for successful completion of

Prevention of Medical Errors

On: 5/21/2020

William A. Cook, Ph.D.
Director, NurseCe4Less.com, Inc.

P.O. Box 17707
Missoula, MT 59808-7707

NurseCe4Less is accredited by the California Board of Registered Nursing. CEP16322

CEUfast NURSING CE

THIS IS TO CERTIFY THAT

Aubree Teribury

HAS SUCCESSFULLY COMPLETED

Diabetic Medications

ANCC CONTACT HOURS: 2.5

CEUFast, Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. ANCC Provider number #P0274.

May 21, 2020

COMPLETION DATE

Julia Tortorice

Julia Tortorice, RN, MBA, MSN, NEA-BC,
Lead Nurse Planner

ceufast.com

CERTIFICATE ID
4753690

VERIFY AUTHENTICITY
Scan QR code OR visit CEUFast.com/verify

Retain this certificate for your records for 6 years. Do NOT send to your licensure board unless requested.

1783

Student and Group Transcript Report

Report Generated: Aug 25, 2019, 1:07 am ET

HealthStream.

Academic Students Non-Employees

Teribury, Aubree

Transcript Range: Aug 26, 2018 through Aug 25, 2019

Report Generated: Aug 25, 2019, 1:07 am ET

CONTINUING EDUCATION EARNED

CREDIT UNITS	NUMBER EARNED
Admin-Entered	0.00
Courses	20.00
Self-Entered	0.00

COMPLETIONS

Total Completions: 18 | Estimated Time: 20:54

NAME	ESTIMATED TIME*	COMPLETION DATE
Perspectives on Prevention: Surgical Site Infections: Target Zero! - CNE	1:15	08/25/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

APEX Innovations: NIH Stroke Scale Training and Certification (free course)	3:00	08/25/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	3.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE	3.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE	3.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

Personal Protective Equipment	1:00	08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

Medication Reconciliation Excellence - 20-655755 — 1:20 — 08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	816520 (NV)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	RN238727 (GA)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	95164504 (CA)

Safe Patient Handling 101 — 1:13 — 08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	1.00 Contact Hour(s)		

PAMG-1 to Aid in the Diagnosis of Premature Rupture of Fetal Membranes - 20-733582 — 0:55 — 08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	816520 (NV)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	RN238727 (GA)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	95164504 (CA)

SAFE Turning and Positioning For Patients and Caregivers - CNE 1.0 Contact Hour(s) — 1:04 — 08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)
CNE	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)

Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) Nursing Intervention Guide - Independent Study	1:01	08/24/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

Science of Fall and Injury Prevention - CNE	1:21	08/22/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

Continuous Pulse Oximetry (AARC/CSRT) - 20-580338	1:00	08/22/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CE	1.00 CRCE		

Spontaneous Preterm Delivery: Biomarkers for Risk Assessment - 20-716620	0:55	08/22/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	816520 (NV)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	RN238727 (GA)
CME/CNE	1.00 AMA PRA Category 1/Contact Hour(s)	Registered Nurses	95164504 (CA)

Alarm Management (AARC/CSRT) - 20-581628	1:00	08/22/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)

CE	1.00 CRCE

Hazardous Drugs and USP<800>: What Nurses Need To Know - CNE	0:42	08/22/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE - California	1.00 CNE	Registered Nurses	816520 (NV)
CNE - California	1.00 CNE	Registered Nurses	RN238727 (GA)
CNE - California	1.00 CNE	Registered Nurses	95164504 (CA)

Bloodborne Pathogens Course - OHS_BIO500	1:23	07/29/2019
Bloodborne Pathogens - 20-414808	1:20	07/29/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

Early Warning Scores: Understanding and Applying the Tool for Nursing Practice	1:05	07/09/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE	1.00 Contact Hour(s)		

Bloodborne Pathogens - 20-414808	1:20	07/09/2019

CREDIT TYPE	CREDIT UNITS	DISCIPLINE	LICENSE # (STATE)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)
CNE - Florida	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)

CNE - California	1.00 Contact Hour(s)	Registered Nurses	816520 (NV)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	95164504 (CA)
CNE - California	1.00 Contact Hour(s)	Registered Nurses	RN238727 (GA)

IRB Initial Training - CITI - IRB_IRBITCITI	0:00	01/08/2019

ADMINISTRATOR-ENTERED

*Estimated Times are stated in hours:minutes format.

LEGEND = Course

HealthStream.

Copyright © 2019 HealthStream, Inc. All Rights Reserved.

Build: 13.01.28.895.636 | O:A00WLC009

HealthStream.

Copyright © 2019 HealthStream, Inc. All Rights Reserved.

Build: 13.01.28.895.636 | AO: 79

Apex Innovations Recognizes That

Aubree Teribury

Has Successfully Completed

NIHSS

NIH Stroke Scale Training & Certification

Online Education - www.apexinnovations.com

And Is Awarded

3.0 contact hours (60 minute contact hour)

Apex Innovations is accredited with distinction as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

95 %

Score

ACCREDITED PROVIDER WITH DISTINCTION

AMERICAN NURSES CREDENTIALING CENTER

ANCC Provider #: P0270

08/24/2019

Examination Date

Apex Innovations

Improving Outcomes Through Education

3909 Ambassador Caffery Parkway Bldg. K

Lafayette, LA 70503

Toll Free: (888) [illegible] 337-210-4500

1789

EXHIBIT "G"

WELLSTAR

May 26, 2020

Dear Sir/Madam

I have been an RN for 33 years both here in the USA and in the UK, working in the field of Women's Heath. My past history includes working as a Certified Nurse Midwife in the UK.

I am at present a Charge Nurse on a very busy Labor and Delivery unit at Wellstar Regional Medical Center where I had the great privilege of working with Aubree Teribury from July 2017 – June 2018 in my capacity as Charge Nurse on Night Shift.

I can say without hesitation that Aubree is a genuinely talented RN, calm, self assured and capable of working in a high stress environment. Her organizational skills are of the highest caliber, which were essential in coping with frequent interruptions, emergencies and unforeseen situations.

In the short time that I worked with Aubree it was obvious that she was dedicated to her patient and their family, always handling every situation with sensitivity, tact and professionalism. Aubree often received compliments from her patients and was a highly respected member of the interdisciplinary team.

Aubree possess' superlative, critical thinking abilities, she is focused, displaying great initiative.

Aubree has a passion for nursing, always eager to learn, and is at present is attending graduate school where she holds a 3.7GPA.

Aubree interacts appropriately with her patients, while carrying out her nursing duties. She is friendly, compassionate and above all honest, which is highlighted in that she freely admits to her mistake.

I think that one mistake should not define her career as nurse. Aubree has a bright future in Nursing, and is a tremendous asset. who I can recommend without any doubt or reservation

Please do not hesitate to contact me if you have any further questions.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge.

Yours sincerely

A. Taylor RN

Alison Taylor
Resource nurse
Labor/APU
Wellstar Regional Medical Center
Marietta
Georgia 30062

Work: 770 793 8350
Cell: [redacted]
taylor.alison@wellstar.org
[redacted]

EXHIBIT "H"

6/12/2020

To Whom It May Concern:

I have been a registered nurse for 12 years with 11 of those years in labor and delivery. In January of 2019, I had the pleasure of meeting and working alongside Aubree at a high risk labor and delivery unit. Since June 2019, I have worked in a charge nurse capacity and have overseen Aubree's work in a low risk labor and delivery unit. During the time I have known Aubree, I have observed her being professional, caring and eager to teach/help the new nurses on the unit.

Aubree is punctual to work and always has a good attitude. She is diligent with her charting and is well liked by her peers and physicians. She demonstrates proper SBAR reporting when collaborating with the physicians and updates them at appropriate times. She has demonstrated excellent skill and expertise in both the high and low risk setting. Aubree has been a great resource for our newer nurses. She has taught the new nurses how to be proactive to achieve safe patient care. She has a calming presence especially during emergencies, which helps facilitate communication.

Aubree has been honest with me regarding the current allegations and in my professional opinion Aubree is fit to practice nursing. She provides safe, competent care to her patients. I look forward to being able to work with Aubree for many years to come.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge.

Kathryn Rasor RN

kathryn.rasor@carsontahoe.org



EXHIBIT "I"

June 4, 2020

To Whom it May Concern,

I am writing this letter to attest to the character and competency of Registered Nurse Aubree Teribury, BSN, RN.

I have been a nurse for 28 years and hold the title of Resource Coordinator RNC-RC at Candler Hospital in Savannah, Georgia in the Labor and Delivery Department. I had the pleasure of working with Aubree Teribury from April 2015 to July 2017. During this time, I held the role of charge nurse on the 7p-7a shift and was instantly impressed by Aubree's readiness to learn and grow her knowledge of the obstetric population. She arrived on the 7p-7a shiftfollowing a short 6-week orientation to the unit and quickly adapted to her new specialty and was always eager to help.

During my time working along side Aubree I found her to be skillful and organized. She frequently cared for either 4 antepartum patients or 2 labor patients at a time as the census needed her to without flaw. Her patients often voiced praise in the care they received from her. As a charge nurse she was someone I always looked forward to having on my shift because I knew her patients would be well cared for and she was always a pleasure to work with. During her time at Candler she never received any discipline or complaints that I am knowledgeable of and was an employee we were saddened to lose when she decided to expand her career in obstetrics and move home to Atlanta. It did not surprise me to find out that since her time at Candler Hospital she had begun graduate school and will be graduating with a Master's in Nursing with a focus in Women's Health in August. I believe she is an asset to the nursing community and has a wonderful future ahead of her as a Women's Health Nurse Practitioner.

With all of this said, I was incredibly surprised to find out that Aubree is having her license and nursing integrity questioned. I am not aware of the full details of the current allegations Ms. Teribury is facing against her nursing license other than that a medication error occurred while she was acting as a travel nurse in California. However, I do know following the error she followed common protocol that is expected when a medication error occurs. She made a report of the error, communicated the error with the physician, and communicated and apologized to the patient and her husband. I believe her willingness to admit to an error and take accountability for it speaks volumes in itself to her character not only as a nurse but as a human.

If you would like to speak with me further regarding any of this I can be reached at [redacted] or [redacted]

I declare under penatly of perjury that the foregoing statements are true and correct to the best of my knowledge.

Sincerely,

Laura N. Morgan, RNC

EXHIBIT "J"

May 28, 2020

Ree A. Standiford, RN

[redacted] Roundstone Way

Richmond Hill, Ga 31324

To Whom It May Concern,

I am writing this letter to attest to the character and competency of Ms. Aubree Teribury, RN

I have been a nurse for 30 years, 27 of which have been in Women's Health, specifically Labor and Delivery and Post Partum Care. I worked with Ms. Teribury from June 2015 to July of 2017 on the LD unit at Candler Hospital in Savannah, Ga. I frequently was the charge nurse on the 7p to 7a shift and Ms. Teribury worked as a staff RN on the unit. When I wasn't in a charge nurse role, I worked along side her as a contemporary. I always found Ms. Teribury to be organized, skillful, and a great team player. She routinely assumed care of actively laboring patients, antepartum patients and infants as the census dictated. I can say that she was liked by fellow co-workers and patients that she cared for. She was always available to help where she was needed most and managed patient care and charting with ease. Ms. Teribury was a valued employee at Candler Hospital and did not have any disciplinary instances to my knowledge. I do not know the specifics of the current allegation other than that it involved a medication error and that Ms. Teribury followed the protocol of reporting the error and notifying appropriate personnel of said error.

During my time of working with Aubree I found her to be a conscientious nurse and one that would follow policies and protocols established by the unit. She always exemplified good communication with the physicians and nurses she worked with and kept the charge nurse updated with current statuses of the patients she was caring for. She gave thorough and accurate reports to physicians and nurses that she was reporting off to.

On a personal note, Aubree was amicable and friendly and a pleasure to work with. When Aubree and I were scheduled on shift together it was reassuring to have a great nurse to work with and one that took great care of her patients.

Thank you for giving me the opportunity to provide this reference for Aubree Teribury. If there is a need to reach me, I can be reached on my cell phone at [redacted]. Additionally, my personal email is [redacted]

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge.

Sincerely,

Ree A. Standiford, RN

Ree A. Standiford, RN

EXHIBIT "K"

Renown HEALTH

June 12, 2020

To whom it may concern,

I am the Manager of Nursing on Labor and Delivery at Renown Regional Medical Center. I have been employed here as an RN since 2006 and have been the manager of this department for the past four years (dating from July 2016).
I am writing in regards to Aubree Teribury. She is currently a Registered Nurse here on Labor and Delivery and has been employed as such since January of 2019. Upon completion of her 4 week orientation period, Aubree was given an OR competency exam as well as an OB competency exam. She scored highly on both, and there were no areas of concern for follow up or remediation. This spring our institution tested knowledge of drip rates and medication calculations of all RNs throughout the organization and Aubree was very knowledgeable and capable in this area as well. With all of this said, I would never question her ability to provide anything but exceptional care. And exceptional care is all I have witnessed.

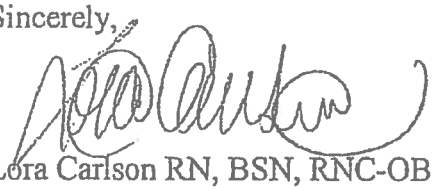
Aubree has excelled in her nursing practice here at Renown. She is timely, detail oriented, and thorough. She has not acquired any corrective actions related to nursing practice. Aubree is careful in her practice and quick to ask for help when or if she needs it. I have not worked side by side with Aubree much as she is a night shift RN. Over the last year and a half I have received many compliments from patients, staff members, and my night shift supervisors regarding Aubree's work ethic. They have all stated she has a high degree of initiative, is knowledgeable and thoughtful in her practice, and that she has strong potential to become a charge RN and preceptor for our unit.

I feel proud to have Aubree working as a nurse on my unit. She is well deserving of her title of "RN" and as I displayed above she has all of the most important attributes a nurse should have. Should you have any additional questions, I would be happy to discuss via telephone or email. Both are listed below.

Renown HEALTH

"I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge."

Sincerely,



Lora Carlson RN, BSN, RNC-OB
Manager of Nursing Renown Regional Medical Center-Labor and Delivery
Lora.Carlson@renown.org
(775) 982-4232

EXHIBIT "L"

May 29, 2020

To Whom it May Concern;

I had the pleasure of working with Aubree Teribury in the Fall of 2018. I was immediately impressed by Aubree's knowledge base and ability to take care of our high risk obstetric population. She quickly adapted to our nursing culture here at Sierra Vista Labor and Delivery and we all saw her as a great asset to our unit.

At the time I met Aubree I had been a labor and delivery nurse for over 10 years and had worked with many different nurses and doctors. I can honestly say that Aubree was one of the best nurses I have had the pleasure of working with. As a nurse I saw first had how Aubree's skill, intelligence and willingness to jump right in benefited not only her patients, but fellow nurses and the unit as a whole. Aubree was very attentive and caring with her patient's, with many of her patient's requesting that she care for them multiple nights in a row.

I was not working the night the medication error took place, but I was working the next night as a relief charge nurse. I was made aware of the incident from the previous night by Aubree herself. Aubree and I then spoke with our Nurse Manager at the time, Sharon Bonifazi, who advised us to inform our OB Hospitalist, Dr. Danny Lickness. Aubree then recounted the incident to Dr. Lickness. Aubree went through the proper channels of informing those of us on who needed to know in the proper way. As a side note, Aubree also informed the patient of the error she had made and apologized. This same patient knowing about the medication error requested to have Aubree as her nurse multiple times after that. I worked alongside Aubree many nights and I was also in charge many of the shifts when Aubree was working. Aubree is one of those nurses that you took a sense in comfort knowing she was working, as you knew her patients would be well cared for and she could jump in and help out in the event of an emergency.

I was very surprised to find out that Aubree is having her license and nursing integrity threatened. She is one of the most honest, capable, intelligent, respectful and well rounded nurses I have worked with, now going on my 13th year as a labor and delivery nurse. If you would like to speak with me further regarding any of this I can be reached at [redacted] or [redacted]

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge.

Best Regards,

Melissa Lawrence, RN

Melissa Lawrence, RN

EXHIBIT "M"

Dear Sirs/Madam:

July 10, 2020

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge.

I was the manager of Women and Children's Services at Sierra Vista Regional Medical Center in 2018 when Aubree Terbury was a traveling RN on our Labor and Delivery Unit. Aubree was working as part of the night shift and was respected by her patients, colleagues and the obstetricians on the unit. In November 2018, Aubree made a serious medication error. I followed up with Aubree to investigate the details of the error. Aubree expressed regret and was shaken up by this event. Aubree and I discussed the error and I found her honest, forthcoming, remorseful. We spoke about how this error could have been prevented. Aubree mentioned that it had been a busy shift and she was stressed at the time of the error. We spoke about safeguards and processes in place that would help prevent this from occurring. Aubree was able to express to me that she understood these processes and was able to state the correct way to draw up insulin, have it independently verified by another RN and to remember that when passing medications, to slow down and devote her attention to only the medication. When I followed up with the patient, she told me that Aubree had been in to speak to her and had apologized to her for making this error. I sincerely feel that Aubree has learned from this error and do not think that she will ever make this type of error again. I hope that she is able to continue in her chosen work and feel that she is safe to continue to work as an RN.

Sincerely,
SBonifazi RNC-NIC, C-NNIC
Sharon Bonifazi RNC-NIC, C-NNIC
Sharon.oneneuronicu@gmail.com

EXHIBIT "N"

My Transcript

Total Claimed Credits: 25.87 CE, 7.25 Rx

Search

Courses

Total Claimed Credits*: 25.87 CE, 7.25 Rx

*For credit to be claimed, all parts of the activity, including the post-test and evaluation, must be completed.

Course Name	Started	Progress	Completed	Credits	Certificate
2018 Overall Evaluation		0 %		0	
WHNP Exam Review: Primary Care: Module 1 (18-02-17)		0 %		1.15 CE, 0.33 Rx (NCC Code 2C)	
WHNP Exam Review: Primary Care: Module 2 (18-02-18)		0 %		1.3 CE, 0.5 Rx (NCC Code 2C)	
WHNP Exam Review: Primary Care: Module 3 (18-02-19)		0 %		2 CE, 1 Rx (NCC Code 2C)	
WHNP Exam Review: Pharmacology: Module 2 (18-02-21)	4/20/2020	100 %	4/20/2020	1.25 CE, 1.25 Rx (NCC Code 4)	View Certificate

WHNP Exam Review: Pharmacology: Module 1 (18-02-20)	4/20/2020	100 %	4/20/2020	1.5 CE, 1.5 Rx (NCC Code 4)	View Certificate
WHNP Exam Review: Obstetric Complications: Module 4 (18-02-16)	4/17/2020	100 %	4/17/2020	0.8 CE, 0.5 Rx (NCC Code 2B)	View Certificate
WHNP Exam Review: Obstetric Complications: Module 3 (18-02-15)	4/17/2020	100 %	4/17/2020	1.25 CE, 0.5 Rx (NCC Code 2B)	View Certificate
WHNP Exam Review: Professional Issues (18-02-22)	4/5/2020	100 %	4/5/2020	0.5 CE (NCC Code 5)	View Certificate
WHNP Exam Review: Obstetric Complications: Module 2 (18-02-14)	4/5/2020	100 %	4/5/2020	1.2 CE, 0.5 Rx (NCC Code 2B)	View Certificate
WHNP Exam Review: Obstetric Complications: Module 1 (18-02-13)	4/5/2020	100 %	4/5/2020	1.25 CE, 0.25 Rx (NCC Code 2B)	View Certificate
WHNP Exam Review: Gynecologic Disorders: Module 6 (18-02-10)	4/5/2020	100 %	4/5/2020	1 CE, 0.25 Rx (NCC Code 2A)	View Certificate
WHNP Exam Review: Gynecologic Disorders: Module 3 (18-02-07)	3/23/2020	100 %	3/23/2020	1.25 CE (NCC Code 2A)	View Certificate

WHNP Exam Review: Gynecologic Disorders: Module 5 (18-02-09)	12/6/2019	100 %	12/6/2019	1 CE, 0.5 Rx (NCC Code 2A)	View Certificate
WHNP Exam Review: Gynecologic Disorders: Module 4 (18-02-08)	12/6/2019	100 %	12/6/2019	1.25 CE (NCC Code 2A)	View Certificate
WHNP Exam Review: Gynecologic Disorders: Module 1 (18-02-05)	12/3/2019	100 %	12/6/2019	3.25 CE, 0.5 Rx (NCC Code 2A)	View Certificate
WHNP Exam Review: Gynecologic Disorders Module 2 (18-02-06)	12/1/2019	100 %	12/3/2019	1 CE, 0.5 Rx (NCC Code 2A)	View Certificate
WHNP Exam Review: Normal Obstetrics: Module 2 (18-02-12)	12/1/2019	100 %	12/1/2019	1 CE (NCC Code 3)	View Certificate
WHNP Exam Review: Normal Obstetrics: Module 1 (18-02-11)	11/29/2019	100 %	11/29/2019	1.75 CE (NCC Code 1)	View Certificate
WHNP Exam Review: Normal Gynecology and Well Woman Care: Module 2 (18-02-04)	11/29/2019	100 %	11/29/2019	1.96 CE, 1 Rx (NCC Code 1)	View Certificate
WHNP Exam Review: Normal Gynecology and Well Woman Care: Module 1 (18-02-03)	10/25/2019	100 %	10/25/2019	1.86 CE (NCC Code 1)	View Certificate

WHNP Exam Review: General Health Assessment and Promotion: Module 2 (18-02-02)	10/25/2019	100 %	10/25/2019	1.5 CE (NCC Code 1)	View Certificate
WHNP Exam Review: General Health Assessment and Promotion: Module 1 (18-02-01)	9/28/2019	100 %	10/25/2019	1.3 CE (NCC Code 3)	View Certificate
Introduction to the WHNP Certification Review and Update: Strategies for Studying and Test Taking (18-02-00)	10/25/2019	100 %	10/25/2019	0	View Certificate

Live Events

Total Claimed Credits: 0

There are no courses to display at this time.

9

9A

4-14-21

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH_____

Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b ☐ Partnership - Pages 1,2,6,10,11a&b

☑ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b ☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Cure 4 The Kids Foundation Patient Pharmacy

Physical Address: 1 Breakthrough Way

City: Las Vegas State: NV Zip Code: 89135 Telephone: 702-732-1493

Fax: 702-732-1080 Toll Free Number: _____

E-mail: pharmacy@cure4thekids.org

Website: cure4thekids.org

Managing Pharmacist: Catherine Boutsikakis License Number: 19624 OK 10/31/21

X100

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☑	☐ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding
		☐	☑ Non Sterile Compounding
All boxes must be checked		☐	☑ Mail Service Sterile Compounding
For the application to be complete		☐	☑ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Christine Tonn
Print Name of Authorized Person

3/26/2021
Date

Board Use Only Date Processed:_____ Amount: $500 Check# 10107133

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: None

Mailing Address: 10170 W Tropicana Ave #156-252

City: Las Vegas State: NV Zip: 89147

Telephone: 702-691-5703 Fax: 702-952-5451

Contact Person: Christine Tonn

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A - Nonprofit
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. N/A - Nonprofit

3) What was the price paid per share? N/A - Nonprofit

List any physician shareholders and percentage of ownership. N/A - Nonprofit

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 12:00 ~~am~~ pm 4:00 pm Saturday N/A _____ am _____ pm

Sunday N/A _____ am _____ pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20071501700

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Christine Tonn

Responsible Person of Alliance for Childhood Diseases dba Cure 4 the Kids Foundation

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Christine Tonn
Print Name of Authorized Person

3/26/2021
Date

Managing Pharmacist

Pharmacist Name: Catherine Boutsikakis License #: 19624

Pharmacy Name: Cure 4 The Kids Foundation Patient Pharmacy

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____
County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature _____ Date 3/29/2021

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **ALLIANCE FOR CHILDHOOD DISEASES**, as a DOMESTIC NONPROFIT CORPORATION (82) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 04/12/2007, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/08/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202101081337894
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

ALLIANCE FOR CHILDHOOD DISEASES
NAME OF ENTITY

NV20071501700
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☑ Nonprofit Corporation (see nonprofit sections below)

☐ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
Barbara K. Cegavske	E0263332007-7
	Filing Number
	20211257080
Secretary of State	Filed On
State Of Nevada	02/24/2021 11:16:17 AM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☑ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE SECRETARY:

Name	Country
RENEE COFFMAN	USA

Address	City	State	Zip/Postal Code
1 BREAKTHROUGH WAY	LAS VEGAS	NV	89135

CORPORATION, INDICATE THE TREASURER:

Name	Country
DAVID LEAKE	USA

Address	City	State	Zip/Postal Code
1 BREAKTHROUGH WAY	LAS VEGAS	NV	89135

CORPORATION, INDICATE THE DIRECTOR:

Name	Country
FARHAN NAQVI	USA

Address	City	State	Zip/Postal Code
1 BREAKTHROUGH WAY	LAS VEGAS	NV	89135

CORPORATION, INDICATE THE DIRECTOR:

Name	Country
CORY FREY	USA

Address	City	State	Zip/Postal Code
1 BREAKTHROUGH WAY	LAS VEGAS	NV	89135

CORPORATION, INDICATE THE PRESIDENT:

Name	Country
ANNETTE L LOGAN-PARKER	USA

Address	City	State	Zip/Postal Code
1 BREAKTHROUGH WAY	LAS VEGAS	NV	89135

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Christine Tonn

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Executive Personnel
Title

02/22/2021
Date

CURE 4 THE KIDS
FOUNDATION
A Division of Roseman University of Health Sciences

CERTIFICATE OF CORPORATE RESOLUTION

Appointing Designated Representative for Retail Pharmacy

We, the undersigned, being all Directors of the Board of Cure 4 The Kids Foundation, organized and existing under the laws of the State of Nevada, and having its principal place of business at 1 Breakthrough Way, Las Vegas, Nevada 89135, herby certify by unanimous written consent in lieu of a meeting, in accordance with all applicable laws, the provisions of the charter, and by-laws of the Corporation, **THEREFORE RESOLVE AS FOLLOWS:**

Catherine Boutsikakis is appointed Designated Representative of Cure 4 The Kids Foundation Retail Pharmacy.

RESOLVED FURTHER THAT the aforesaid power entrusted to the said representative shall be valid and effective unless revoked further earlier by the Board or shall be exercisable by her so long as she is in good standing with the Company.

By affirmative votes noted as signatures below, we, the Board of Cure 4 The Kids Foundation with authority to bind the Company, approve the form and content of this resolution, to be effective immediately.

DIRECTORS

Annette Logan-Parker	04-08-2021
	Date
David Leake	4-9-2021
	Date
Dr. Renee Coffman	4/12/21
	Date
Cory Frey	4/12/21
	Date
Farhan Naqvi	4/12/21
	Date

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date 3/29/2021

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Retail Pharmacy
(Nature of Pharmacy or Wholesaler)

Cure 4 The Kids Foundation Patient Pharmacy 1 Breakthrough Way Las Vegas, NV 89135
(Name and Address of Business for Which Designated Representative is Requested)

N/A
(If applicable, Name Under Which It is Now Operated)

1. PERSONAL INFORMATION:

Last Name	First Name	Middle Name
Boutsikakis	Catherine	

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise): Catherine Pervolarakis

Present Residence Address-Street or RFD	City	State/Zip
[redacted] Clear River Falls Ln	Henderson	NV 89012

Present Business Address	Dates	City	State/Zip
1 Breakthrough Way		Las Vegas	NV 89135

Present Position with the Pharmacy or Wholesaler: Pharmacist — Dates: 5/1/2020-present

Phone: Residence [redacted]

Business (702)732-1493

[redacted]
Date of Birth

Brooklyn, Kings, NY
Place of Birth (City, County, State)

50 — Age

[redacted]
Social Security Number or ITIN

F
Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Brown	White	132		5'4"

Scars, tattoos or distinguishing marks and/or characteristics: None

Are you a citizen of the United States? Yes ✓ No ☐ If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ✓ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial CB

MARITAL INFORMATION-Continued

A. **Current Marriage** 03/09/2002 (Date) Brooklyn, Kings, NY (City, County and State)

Spouse's full name (Maiden) Andrew Boutsikakis SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth Queens, NY

Resident address [redacted] Clear River Falls Ln (Street) Henderson (City) NV (State) 89012 (Zip)

Telephone: Residence [redacted] Business (917)776-0228

Spouse's employer Self Occupation Consultant

Address of employer [redacted] Clear River Falls Ln (Street) Henderson (City) NV (State) 89012 (Zip)

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

N/A

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. **FAMILY INFORMATION:**

A. **Children and Dependents**:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
George Boutsikakis	[redacted]		[redacted] Clear River Falls Ln
Michael Boutsikakis	[redacted]		[redacted] Clear River Falls Ln

B. **Child Support Information:**

Please mark the appropriate response:

- ✓ I am not subject to a court order for the support of child.
- I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial [redacted]

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name_____

Address_____

Contact person_____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Chris Pervolarakis	[redacted]	[redacted] Petersons Ln SI,NY	Electrician
Mother	Irene Pervolarakis	[redacted]	[redacted] Petersons Ln SI,NY	Homemaker
Father-in-Law	George Boutsikakis	[redacted]	[redacted] E Empire Cr SLC,UT	Restauranteur
Mother-in-Law	Katina Boutsikakis	[redacted]	[redacted] E Empire Cr SLC,UT	Homemaker

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Kostas Pervolarakis	[redacted]	[redacted] Amboy Rd SI,NY	Electrical Engineer
Spouse	Pauline Panagiotakis	[redacted]	[redacted] Amboy Rd SI,NY	Fitness trainer
	Anthony Pervolarakis	[redacted]	[redacted] Newark St Hoboken, NJ	Electrician
Spouse	Ana De Paola	[redacted]	[redacted] Newark St Hoboken, NJ	Homemaker
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	PS105/PS127/IS201	Brooklyn, NY	9/1975-6/1985	Yes ✓ No
High School	Fontbonne Hall Academy	Brooklyn, NY	9/1985-6/1988	Yes ✓ No
College University	St. John's University	Jamaica, NY	9/1988-5/1993	Yes ✓ No
Other				Yes No

Type of degree obtained, if any B.S. Pharmacy

College or university where obtained St. John's University

Applicant's initial OB

March 11, 2020

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☚ No ✓

Branch_____ Date of entry-active service_____

Date of separation_____ Type of discharge_____

Rating at separation_____ Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☚ No (☚) If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☚ No ✓

County_____ State_____ Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☚ No ✓ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☚ No ✓ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☚ No ✓

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☚ No ✓

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☚ No ✓

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☚ No ✓
If yes, when?_____ city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☚ No ✓
If yes when?_____ city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☚ No ✓
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial CB

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
7/2016-present	[redacted] Clear River Falls Ln	Henderson	NV
7/2015-7/2016	1724 Sandstorm Dr	Henderson	NV
8/2014-7/2015	1410 E Tomahawk Dr	Salt Lake City	UT
3/2007-8/2014	921 83rd St.	Brooklyn	NY
3/2002-3/2007	975 79th St.	Brooklyn	NY
7/1979-3/2002	673 85th St.	Brooklyn	NY

Applicant's initial 

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
5/2020-present	Cure 4 The Kids Foundation	1760
Title	**Description of Duties**	**Name of Supervisor**
Pharmacist	Management	Jennifer Buitrago

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
8/2007-8/2014	Pollina Pharmacy	7280
Title	**Description of Duties**	**Name of Supervisor**
Pharmacist	Filling prescriptions; Patient Counseling	Roberto Pollina

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
9/1993-2/2006	Genovese/Eckerd Drug Stores	27,040
Title	**Description of Duties**	**Name of Supervisor**
Supervising Pharmacist	Filling prescriptions, counseling, management	Nick Aloi

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial 

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City State Zip	Telephone	Years Known
Name Helen Kourlas	Home	[redacted]Dutchess Ave SI NY 10301	[redacted]	27 years
Employer Health First	Business	100 Church St NY NY10007	(212)209-6456	
Name Cherelyn Karras	Home	[redacted] Miles Ave Albertson NY 11507	[redacted]	30 years
Employer NY Blood Center	Business	1200 Prospect Ave Westbury NY 11590	(516)478-5049	
Name Denise Murach	Home	[redacted] Indepence Ave Brooklyn NY 11228	[redacted]	33 years
Employer Rite Aid	Business	8222 18th Ave Brooklyn, NY 11214	(718)644-6012	
Name Eugenia Cho	Home	[redacted]Chalet Hills Terr Henderson NV 89052	[redacted]	45 Years
Employer Simply Vegas	Business	1780 W Horizon Ridge Pkwy Henderson NV 89012	(702)283-0439	
Name Jo Ann Davaris	Home	[redacted] Sunnyhill terr River Vale NJ 07675	[redacted]	25 years
Employer Booking Holdings	Business	800 Connecticut Ave Norwalk, CT 06854	(203)822-3722	

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑

If yes, state type, where and years held

.....

.....

.....

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

.....

.....

.....

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

.....

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

.....

If yes to the above, state where, when and for what reason:

.....

.....

Applicant's initial _____

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ✓ No

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ✓ No

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes No ✓

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes No ✓

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ✓ No

19. **Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler?** Yes ✓ No

20. **Will you be employed fulltime with the pharmacy or wholesaler?** Yes ✓ No

21. **Will you be present at the site of the pharmacy or wholesaler during its normal operating hours?** Yes ✓ No



Date of photograph 4/12/2021

Applicant's initial

STATE OF Nevada

ss.

COUNTY OF Clark

I, Catherine Boutsikakis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 12 day of April 2021

Notary Public

ARACELI DELEON
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 20-3756-01
My Appt Expires February 10, 2024

(seal)

Applicant's initial

9B

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH_____

Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☑ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Elemental Pharmacy

Physical Address: 6330 South Eastern Avenue Suite 1A

City: Las Vegas State: NV Zip Code: 89119 Telephone: (800) 201-4223

Fax: (702) 922-3791 Toll Free Number: _____

(800) 201-4223 E-mail: admin@elementalpharmacy.com

Website: TBD

Managing Pharmacist: Jenner Sinang License Number: 18954

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding
		☐	☑ Non Sterile Compounding
All boxes must be checked		☐	☑ Mail Service Sterile Compounding
For the application to be complete		☐	☑ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Randy L. Case
Print Name of Authorized Person

8/20/20
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: Elemental Pharmacy

Mailing Address: 6330 S Eastern Suite 1A

City: Las Vegas State: NV Zip: 89119

Telephone: (800) 201-4223 Fax: (702) 922-3791

Contact Person: Randy Case

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Randy Case (Name) 6330 S Eastern Ave Suite 1A, Las Vegas, NV 89119 (Business Address)

b) _____ (Name) _____ (Business Address)

c) _____ (Name) _____ (Business Address)

d) _____ (Name) _____ (Business Address)

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? $1

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday	10:00 am	5:00 pm	Saturday	10:00 am	2:00 pm
Sunday	Closed am	Closed pm	24 Hours	N/A	

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Randy Case

Responsible Person of Elemental Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Randy Case
Print Name of Authorized Person

8/14/2020
Date

Managing Pharmacist

Pharmacist Name: Jenner Sinang License #: 18954

Pharmacy Name: Elemental Pharmacy

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature _____ Date 8/14/2020

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Elemental Pharmacy LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 08/18/2020, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/18/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202008181013037
You may verify this certificate online at http://www.nvsos.gov

Elemental Pharmacy LLC

List of Officers and Directors:

Randy Case – Director, President

admin@elementalpharmacy.com

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date August 11, 2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy License
(Nature of License)

Elemental Pharmacy 6330 South Eastern Suite 1A Las Vegas, NV 89119
(Name and Address of Establishment for Which License Is Requested)

(If applicable, Name Under Which It Is Now Operated)

1. PERSONAL INFORMATION:

Case	Randy	Lee
Last Name	First Name	Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Spiracle Ave	Henderson	Nevada, 89002
Present Residence Address-Street or RFD	City	State/Zip
6330 Eastern 1/1/2021	Las Vegas	Nevada 89119
Dates		

Present Business Address	City	State/Zip
Owner/Operations 1/1/2021		Nevada
Dates		

Occupation		Phone: Residence
	Pocatello, idaho	Business TBD

Date of Birth	Place of Birth (City, County, State)	
59		Male
Age	Social Security Number or ITIN	Sex

Blue	Blong/grey	Caucasion	225	muscular	6 feet 2 inches
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics Scars on right ankle from surgery

Are you a citizen of the United States? (Yes) X No If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single Married (Separated X) Divorced Widowed Engaged

Applicant's initial RLC RLC

A. **Current Marriage** Separated Date Ashley Brooke Case City, County and State

Spouse's full name (Maiden) SS# or ITIN

Date of Birth Place of Birth Los Angeles

Resident address Alameda Ave Burbank California 91506
Street City State Zip

Telephone: Residence Business None

Spouse's employer LAUSD Occupation Teacher/Librarian

Address of employer PO Box 513307, Terminal Annex Los Angeles Ca 90051-1307
Street City State Zip

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Michelle Marie Case	July 1995	July 1983	Irreconcilable Diff.	Northglen, Co

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Sarah marie Case		los Angeles	Alameda Ave, Burnank, Ca 91506

B. Child Support Information:

Please mark the appropriate response:

- [x] I am not subject to a court order for the support of child.
- [ ] I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- [ ] I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial RLC

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address

Contact person

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Clarence E Case		E d Place, Yuma, Az 85365	retired
Mother	Ethel M Case		E d Place, Yuma, Az 85365	Retired
Father-in-Law	None			
Mother-in-Law	None			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Gary E Case		San Diedo, Ca	Glazer
Spouse				
	Cheryl M Case		None	Deceased
Spouse				
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Kohl Elementary School	Broomfield, Co	1967-1972	X Yes No
High School	Broomfield High School	Broomfiled,.Co	1973-1979	X Yes No
College University	University of Colorado	Boulder, Colo	1981-1984	X Yes No
Other	Pepperdine University	Malibu, Ca	1992-1996	X Yes No

Type of degree obtained, if any Civil Engineering BS and Masters in Business Administration

College or university where obtained University of Colorado and pepperdine University

Applicant's initial RLC

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☚ No x

Branch_____ Date of entry-active service_____

Date of separation_____ Type of discharge_____

Rating at separation_____ Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☚ No ☚ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☚ No ☚

County_____ State_____ Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☚ No ☚ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
June 2005		DUI	Encino, Ca	July 2005	CHP

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☚ No x If yes. furnish details on page 10

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☚ Nox ☚

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☚ No ☚ x

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☚x No ☚

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☚ No x
If yes, when?_____ city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☚ No x ☚
If yes when?_____ city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☚ No x ☚
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

in my job at the Metropolitan water District I was the director of real estate and had gto testify many times

in Eminent Domain trials.

Applicant's initial RLC RLC

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☒ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
1995-1999	13914 Bora Bora Way, #218D	Marina Del Rey	California
1999-2001	3415 Rowena Ave	Los Angeles	California
2001-2003	12021 Laurel Terrace Drive	Studio City	California
2003-2012	4852 Belligham Ave	Valley Village	California
2012-2018	11312 Huston Street #5	North Hollywood	California
2018-2019	Hartsook Street	Sherman Oaks	California

Applicant's initial RLC

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
09/1979-1984	University of Colorado, Boulder, Colo.	graduated from college
Title	**Description of Duties**	**Name of Supervisor**
Studebt Asst	Worked for Engineering Dept	Professor Johnson
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
6/84-6/86	Civil Engeering Design Company, Denver, Colo	Took Better Job
Title	**Description of Duties**	**Name of Supervisor**
Civil Engineer	Design Civil Engineering Projects	Bob
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
6/86-10/88	City of Westminster, Colorado	Took a Better Job
Title	**Description of Duties**	**Name of Supervisor**
Civil Engineer	Planning and Civil Engineering for city Projects	Rick Mark
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
10/88-10/97	Metropolitan Water District of So Cal, Los Angeles	Started my own Company
Title	**Description of Duties**	**Name of Supervisor**
Dir of Real Estate	Managed all the real estate assets of the District	Gary - Chief Engineer
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
10/97-10/99	Strategic Realty Group, Los Angeles, Ca	Took a Better Job
Title	**Description of Duties**	**Name of Supervisor**
Owner/CEO	Real estate Consulting	Myself
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
10/99-3/2008	XO Communications, Reston Virginia	Outsourced our Dept.
Title	**Description of Duties**	**Name of Supervisor**
Dir of Real Estate	managed real estate portfoliio in North Amerca	Ron Scott
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
4/04-6/10	PDCC Development, LLC	Financial Crash in US
Title	**Description of Duties**	**Name of Supervisor**
15% Owner/site manager	redo golf course and develop home sites	Board
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
7/10-7/18	Strategic Energy Marketing, los Angeles, Ca	better opportunity
Title	**Description of Duties**	**Name of Supervisor**
50% owner and CEO	Energy Consulting	Randy Case

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial RLC

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Michael Gennawey	Home	E Burnuda Street, Long Beach 90814				11
Employer SEM	Business	Energy Consulting Business				
Name Tomas Perez	Home	Bordeaux, Trabuco Canyon, Ca 92679				12
Employer CWE	Business	Crypto Software				
Name Vernon Tucker	Home	h Street, Simi Valley, Ca 93065				5
Employer Lawyer - self	Business	Practices Family Law				
Name Larry kosmont	Home	n Street, Manhattan Beach, Ca. 90266				25
Employer The Kosmont Co.	Business	Real Estate Planning and Consulting				
Name Jan Bradford	Home	kirk Street, Sylmar, Ca. 91342				25
Employer Food For Less	Business	Grocery Store Manager				

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☚ No x☚
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☚ No ☚
If yes, state type, where and years held

Professional Engineering License in Colorado 1986- ? and California 1990 - ?

Real Estate Brokers License 1996-2020

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☚ X No ☚
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

See Page 10

Applicant's initial RLC

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☚ No ☚x

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☚ No ☚

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☚ No xx ☚

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☚ No x ☚

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☚ No X

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☚ No x ☚

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☚ No x ☚



Date of photograph 8/18/20

Applicant's initial KLC

STATE OF California
ss.
COUNTY OF Orange

I, Randy Lee Case, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 18th day of August, 2020

Hob Chen
Notary Public

HOB CHEN
COMM. # 2300786
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. AUG. 31, 2023

(seal)

Applicant's initial

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

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 18th day of August, 2020, by Randy Lee Case,

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



(Seal)

Signature

Question 8 continued:

7/18-Present	Elemental Pharma, Inc	Still in the position
CEO	Hemp Related Business	Board

Question 12 Contuinued:

1. Strategic Realty Group - California and Los Angeles
   Real Estate Brokers License - Califonia..... Business License City of Los Angeles
   Randy Case sole owner

2. Strategic Energy Marketing - California
   Business License - California
   Randy Case and Michael Gennawey owners

3. PDCC Development, LLC - Palm Desert, California
   Business licenses for Golf Course, Restaurant and Bar
   Randy Case - 15%, Larry Kosmont - 15%, Sung Sang Cho - 70%

Mark I. Sedar

From: randy case <rle
Sent: Monday, May 10, 2021 10:51 AM
To: Mark I. Sedar
Cc: Jenner Sinang
Subject: Fwd: Elemental Pharmacy - Pharmacy application (additional documents being requested by the NV board of pharmacy before the board meeting, is it needed for us to make the June aganda?)
Attachments: Elemental_Good_Standing_05032021.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Mark, in response to your email dated April 8, 2021 below are the responses you requested. We have attached the Certificate of Good Standing for the Company.

1. Yes Jenner Sinang will be the Managing Pharmacist

2. The updated Certificate of Good Standing is attached below.

3. In the application we submitted I disclosed the DUI I got back in June of 2005. I will expand on that incident. I was at a party in Studio City, California for a birthday celebration for friends of my wife and I. I left the party around 9-10PM and had to take the 101 Freeway to get home. I was speeding a little over the limit and a motorcycle LAPD pulled me over for speeding. Once he approached me he could smell alcohol. I took a breathalyzer and it turned out over the limit to drive with. They arrested me and took me to the Van Nuys jail where I bailed out in about 4 hours. The bail was $5,000 and the court dates were set. I had a business partner Robert Corado who was a lawyer and represented me. Unfortunately he passed away a number of years ago. The DMV took my license for 3 months and I had to attend alcohol classes and 12 AA meetings. There were fines I paid. There was no jail time or anything like that. There have been no incidents since that one in 2005 and I still to this date attend AA meetings. I have moved several times since that incident so I am sure I threw away any documents about that incident because it was so long ago and there was no need to keep those documents. I hope this has helped better describe that incident.

4. Yes I would change #5 to yes because I lost my California Driver's License for 3 months based on the event described above in #4. The explanation they are asking for on page 2 is stated above. When I filled out the application the first time I was thinking about pharmacy licenses and the like. If you mean any license then the answer should be yes to #5 on Page two of application.

Again thank you for the opportunity to be a part of the Pharmacy family in Nevada.

Warm regards,

Randy L Case
Chief Executive Officer
Elemental Pharma, Inc.
(714) Mobile
randy.case@elementalpharmainc.com

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE for a Pharmacy or Wholesaler located in Nevada

Date 06/17/2021

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of Pharmacy or Wholesaler

Elemental Pharmacy / 6330 South Eastern Avenue Suite 1A Las Vegas, NV 89119
Name and Address of Business for Which Designated Representative is Requested

If applicable, Name Under Which It is Now Operated

1. PERSONAL INFORMATION:

Sinang	Jenner	Uy
Last Name	First Name	Middle Name

n/a
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

Alphonse Drive	Las Vegas	NV / 89122
Present Residence Address-Street or RFD	City	State/Zip

Dates

Present Business Address	City	State/Zip

Dates

Present Position with the Pharmacy or Wholesaler

Phone, Residence . . --

Business (702) 992 - 3791

Manila, Philippines
Date of Birth — Place of Birth (City, County, State)

43 years old		Male
Age	Social Security Number or ITIN	Sex

Brown	Black	Beige	200 lbs	Medium	5'-10"
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics none

Are you a citizen of the United States? (Yes) No If alien, registration No

If naturalized, certificate No Date Febuary 10th, 1997

Place Newark, New Jersey (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

(Single) Married Separated Divorced Widowed Engaged

Applicant's initial JS

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name_____

Address_____

Contact person_____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Emiliano Sinang		Sophie Court Sugar Land,Texas 77479	Retired
Mother	Nancy Sinang		Sophie Cour Sugar Land, Texas 77479	Retired
Father-in-Law				
Mother-in-Law				

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Jennifer Potato		Sophie Court Sugar Land, TX 77479	Registered Nurse
Spouse	Albert Potato		Sophie Court Sugar Land, TX 77479	Registered Nurse
Spouse				
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Our lady of Grace Montessori	Manila, Philippines		Yes (No)
High School	Kearny High School	Kearny, New Jersey	1991 to 1995	Yes (No)
College University	Temple University College of Pharmacy	Philadelphia, PA	2004 to 2008	Yes (No)
Other	University of Virginia	Charlottesville, VA	1998 to 2000	Yes (No)

Type of degree obtained, if any Doctor of Pharmacy (PharmD) and Bachelor of arts in Biology

College or university where obtained PharmD from Temple University / BA in Biology from University of Virginia

Applicant's initial JS

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes → (No) →

Branch_____ Date of entry-active service_____

Date of separation_____ Type of discharge_____

Rating at separation_____ Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes → No → If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? (Yes) → No →

County Hudson State New Jersey Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes → (No) → If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes → (No) → If yes, furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes → (No) →

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes → (No) →

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes → (No) →

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes → (No) →
If yes, when?_____ city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes → (No) →
If yes when?_____ city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes → (No) →
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial JS

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes → No → (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes → No → If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
2020 to 2021	Alphonsa Drive	Las Vegas	Nevada
2010 - 2021	540 King Galloway Drive	Lewisville	Texas
2008 - 2010	15150 Blanco Road	San Antonio	Texas
2004 to 2008	7900 Lindberg Blvd	Philadelphia	Pennsylvania
2002 to 2004	4406 Sophie Court	Sugar Land	Texas
1998 to 2002	4428 Plantation Road	Roanoke	Virginia

Applicant's initial JJ

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

05/2008 Walgreens Pharmacy / 410 West Cypress St. San Antonio, TX 78212

40 hours a week (Greater than > 6,000 hours)

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Staff Pharmacist	Filling and verifying prescriptions. Counseling patients.	Alycen Lacombe
Title	Description of Duties	Name of Supervisor
Staff Pharmacist		40 hours a week (Greater than > 6,000 hours)

08/2010 John Peter Smith Hospital / 1500 South Main St Forth Worth, TX 76104 — 40 Hours a week (Greater than > 6,000 hours)

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Staff Pharmacist	Filling and verifying prescriptions. Counseling patients.	Bailey Tyler
Title	Description of Duties	Name of Supervisor
04/2015	Walmart Pharmacy / 7451 McCart Ave Forth Worth, TX 76133	40 hours a week (over than 6,000 hours)

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Staff Pharmacist	Filling and verifying prescriptions. Counseling patients	Rebecca Rodriguez
Title	Description of Duties	Name of Supervisor
Staff Pharmacist	Walmart Pharmacy / 7200 Arroyo Crossing Pkwy, Las Vegas, NV 89113	40 Hours a week (Greater than > 6,000 hours)

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
12/2012	University Medical Center / 1600 West Charleston Blvd. Las Vegas, NV 89102	40 hours a week (Greater than > 6,000 hours)
Title	Description of Duties	Name of Supervisor
Inpatient Staff Pharmacist	Entering and verifying prescription orders including general ambulatory, nicu, picu, ED	Mary Staples

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
05/2017	The Woodlands Apothecary / 8360 Lyndon B Johnson Freeway STE 215 Dallas, TX 75243	40 hours a week (Greater than > 6,000 hours)
Title	Description of Duties	Name of Supervisor
Pharmacy Manager	Verify prescriptions and monitor transactions within the pharmacy to maintain control of pharmaceutical materials and guarantee adherence thereof with applicable state and federal laws. Educate pharmacy staff on policies, reporting guidelines, and expectations as they relate to best quality practices	Angie Bush

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
09/2020	West Plano Pharmacy / 4100 West 15th Street STE 204 Plano, TX 75093	40 hours a week (Greater than > 6,000 hours)
Title	Description of Duties	Name of Supervisor
Pharmacy Manager	Responsible for overseeing the daily business operations of a pharmacy, including dispensing prescription medication and advising clients. Other duties entail managing the pharma	Sam Gupta

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
06/2021	Indespensable Health / 114 E Michigan Ave Suite 2, Grass	24 hours a week

Title	Description of Duties	Name of Supervisor
Telepharmacist	Responsible for order entry and / or verification, providing pharmaceutical information, and maintaining quality assurance for patient care, according to professional standards and state and federal legal requirements	Chris Brettfeld

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initials _____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Mollie Harlow	Home					
Employer Walmart Pharmacy	Business	2310 E Serene Ave Las Vegas, NV 89123			(479) 886 - 5899	5 years
Name Rebecca Rodriguez	Home					
Employer Walmart Pharmacy	Business	7451 McCart Ave Forth Worth, TX 76133			(817) 361 - 7284	5 years
Name Trang Tran	Home					
Employer Walgreens Pharmacy	Business	7200 Arroyo Crossing Parkway Las Vegas, NV 89113			(702) 496 - 8604	5 years
Name Caroline Tabe	Home					
Employer John Peter Smith Hospital	Business	1500 South Main St Forth Worth, TX 76104			(817) 657 - 7796	10 years
Name Bailey Tyler Wynne	Home	1500 South Main St Forth Worth, TX 76104				
Employer John Peter Smith Hospital	Business	1500 South Main St Forth Worth, TX 76104			(903) 245 - 0051	10 years

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes — (No) —

If yes, state type, where and years held

.....

.....

.....

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes — (No) —
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

.....

.....

.....

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes — (No) —

.....

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes — (No) —

.....

If yes to the above, state where, when and for what reason:

.....

.....

Applicant's initial JS

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes No

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes No

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes No

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes No

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes No

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes No

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes No

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes No

ATTACH PHOTOGRAPH
TAKEN WITHIN LAST
30 DAYS HERE

Date of photograph 08/18/2020

Applicant's initial JS

STATE OF Texas

SS.

COUNTY OF Denton

I, JENNIFER SINANG, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 6th day of July, 2021

Notary Public

JASMINA HANSEN
Notary ID #128324740
My Commission Expires
July 12, 2022

(Seal)

Applicant's initial JS

Applicant's initial JS

THE UNITED STATES OF AMERICA

CERTIFICATE OF NATURALIZATION

No.

Personal description of holder as of date of naturalization:

Date of birth:

Sex: MALE

Height: 5 *feet* 06 *inches*

Marital status: SINGLE

Country of former nationality:

PHILIPPINES



INS Registration No.:

I certify that the description given is true, and that the photograph affixed hereto is a likeness of me.

Jenner Sinang

(Complete and true signature of holder)

Be it known that, pursuant to an application filed with the Attorney General

at: NEWARK, NJ

The Attorney General having found that:

JENNER SINANG

then residing in the United States, intends to reside in the United States when so required by the Naturalization Laws of the United States, and had in all other respects complied with the applicable provisions of such naturalization laws and was entitled to be admitted to citizenship, such person having taken the oath of allegiance in a ceremony conducted by the

U.S. IMMIGRATION & NATURALIZATION SERVICE

at: NEWARK, NJ *on:* FEBRUARY 10TH, 1997

that such person is admitted as a citizen of the United States of America.

IT IS PUNISHABLE BY U. S LAW TO COPY, PRINT OR PHOTOGRAPH THIS CERTIFICATE, WITHOUT LAWFUL AUTHORITY.

Commissioner of Immigration and Naturalization

DEPARTMENT OF JUSTICE

FORM N-550 REV. 6-91

1864

AFFIDAVIT

The State of Nevada)

) S.S.

County of Clark)

I, Randy Lee Case, of Las Vegas, in Clark County, Nevada, MAKE OATH AND SAY THAT:

1. My birthdate is [redacted].

2. I currently reside at [redacted] W. Warm Springs Road, unit #[redacted], Henderson, Nevada 89014.

3. I have submitted an application for Elemental Pharmacy to the Nevada Board of Pharmacy.

4. I, Randy Lee Case, will not now nor ever place any hemp (CBD) related products from Spire Wellness, LLC or any other hemp (CBD) company in Elemental Pharmacy. If, for whatever reason, there are hemp related products in Elemental Pharmacy, I will hereby, effective immediately, surrender my Nevada Pharmacy license for Elemental Pharmacy to the Nevada Board of Pharmacy for the duration of the current licensing period.

STATE OF NEVADA

COUNTY OF CLARK

SUBSCRIBED AND SWORN TO BEFORE ME, on the 16th day of June, 2021

Signature _____

(Seal)

NOTARY PUBLIC

My Commission expires:

02 · 18 2025

WOLFGANG WOLLET
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 17-1243-1
My Appt. Expires February 18, 2025

_____
(Signature)

Randy Lee Case

©2002-2021 LawDepot.com®

Count of NDC	Month	
Product_name_txt	4	
ACETAMINOPHEN/CODEINE	4	Controlled
ACETAMINOPHEN/CODEINE PHO SPHATE	5	Controlled
ALPRAZOLAM	1	Controlled
BACLOFEN	9	Non-Controlled
CARISOPRODOL	1	Controlled
CELECOXIB	5	Non-Controlled
CYCLOBENZAPRINE HYDROCHLO RIDE	68	Non-Controlled
DICLOFENAC POTASSIUM	2	Non-Controlled
DICLOFENAC SODIUM	151	Non-Controlled
DICLOFENAC SODIUM DR	19	Non-Controlled
DICYCLOMINE HYDROCHLORIDE	1	Non-Controlled
DULOXETINE HYDROCHLORIDE	1	Non-Controlled
ETODOLAC	11	Non-Controlled
GABAPENTIN	26	Non-Controlled
HYDROCODONE/ACETAMINOPHEN	21	Controlled
IBUPROFEN	68	Non-Controlled
LAMOTRIGINE ODT	2	Non-Controlled
LIDOCAINE	16	Non-Controlled
LIDOCAINE PAIN RELIEF PAT CH	15	Non-Controlled
LIDOCAINE PATCH 5%	1	Non-Controlled
LIDOCAINE/PRILOCAINE	53	Non-Controlled
MELOXICAM	134	Non-Controlled
META	1	Non-Controlled
METHADONE HCL	1	Controlled
METHOCARBAMOL	35	Non-Controlled
METHYLPREDNISOLONE	1	Non-Controlled
METHYLPREDNISOLONE DOSE P ACK	1	Non-Controlled
MODERN	3	Non-Controlled
MORPHINE SULFATE ER	1	Controlled
NAPROXEN	95	Non-Controlled
NORTRIPTYLINE HYDROCHLORI DE	3	Non-Controlled
NURTEC	2	Non-Controlled
OXYCODONE HYDROCHLORIDE	4	Controlled
OXYCODONE/ACETAMINOPHEN	3	Controlled
PIROXICAM	4	Non-Controlled
PREGABALIN	2	Non-Controlled
SALONPAS PAIN RELIEVING G EL-PATCH	1	Non-Controlled
SENNA	1	Non-Controlled
SERTRALINE HYDROCHLORIDE	1	Non-Controlled
TIZANIDINE HCL	29	Non-Controlled
TIZANIDINE HYDROCHLORIDE	156	Non-Controlled
TOPIRAMATE	1	Non-Controlled
TRAMADOL HCL	4	Non-Controlled
TRAZODONE HYDROCHLORIDE	4	Non-Controlled
ZOLPIDEM TARTRATE	1	Controlled
Grand Total	968	

Controlled	42	4.2%
Non-Controlled	968	95.8%



9C

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐New Pharmacy or ☒Ownership Change (Provide current license number if making changes: PH IA03291
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☒ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Elite Medical Center, an extension of Valley Hospital Pharmacy

Physical Address: 150 E Harmon Avenue

City: Las Vegas NV State: Zip Code: 89109 Telephone: (702) 546-0911 Fax: (702) 546-5040 Toll Free Number: N/A

E-mail: jenniferm.rogers@uhsinc.com

Website: TBD

Managing Pharmacist: Jennifer M. Rogers License Number: 18227

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☒ Retail	☐	☒ Off-site Cognitive Services
☒	☐ Hospital (# beds 22)	☐	☒ Parenteral
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☐	☒ Mail Service
☐	☒ Community	☐	☒ Long Term Care
☒	☐ Other: Freestanding Emergency Department	☐	☒ Sterile Compounding
		☐	☒ Non Sterile Compounding
	All boxes must be checked	☐	☒ Mail Service Sterile Compounding
	For the application to be complete	☒	☐ Other Services: Automatic Dispensing Machine

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Steve Filton, Authorized Official
Print Name of Authorized Person

5/27/2021
Date

Board Use Only	Date Processed:	Amount: 500 Check # 1019460756

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Valley Health System LLC

Business Name: Elite Medical Center, an extension of Valley Hospital Pharmacy

Current Business Address: 150 E Harmon Avenue

City: Las Vegas State: NV Zip Code: 89109

Telephone: (702) 546-0911 Fax: (702) 546-5040

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: %:

Name: %:

Name: %:

Hours of Operation for the pharmacy:

Monday thru Friday _____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours X

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV19981003340

Include with the application for a sole owner

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Steve Filton

Responsible Person of Valley Health System LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Steve Filton, Authorized Official
Print Name of Authorized Person

5/27/2021
Date

Managing Pharmacist

Pharmacist Name: Jennifer M Rogers License #: 18227

Pharmacy Name: Elite Medical Center, an extension of Valley Hospital

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☒
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____
County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Jennifer M Rogers — Signature

5/27/2021 — Date

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Elite Medical Center, An extension of Valley Hospital

Physical Address: 150 E. Harmon Avenue

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Jennifer Middle: Mary Last: Rogers

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

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

Mailing Address: [redacted] Yellow Shadow Ave

City: Las Vegas State: NV Zip: 89149

Telephone: [redacted] Email: [redacted]

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

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

Date of Service: From: 04/16/1975 to: 04/27/1978

Military Occupation/Specialty: Communications

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ■ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials: JMP 1

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

School Name		From - To (MM/YY – MM/YY)	
Midwestern University Chicago School of Pharmacy		08/2005-05/2008	
Address	**City**	**State**	**Zip**
555 31st Street	Downers Grove	NV	60515
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Midwestern University Chicago School of Pharmacy		09/1997-05/2020	
Address	**City**	**State**	**Zip**
555 31st Street	Downers Grove	NV	60515
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Lincoln Land Community College		1997	
Address	**City**	**State**	**Zip**
5250 Shepherd Road	Springfield	IL	62703
Diploma/Degree obtained, if any			
Associate Degree in Science			
School Name		**From - To (MM/YY – MM/YY)**	
Sacred Heart-Griffin High School (Sacred Heart Academy)		1968-1972	
Address	**City**	**State**	**Zip**
1200 West Washington	Springfield	IL	62702
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2016-present	[redacted]Yellow Shadow Ave	Las Vegas	NV	89149
03/2012-03/2016	1901 Bradbury Circle	Las Vegas	NV	89129
11/1988-03/2012	2404 South College	Springfield	IL	62704

Applicant's Initials _____ 2

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

Business Name			From - To (MM/YY – MM/YY)
Valley Hospital Medical Center			07/2012-present
Business Address	**City**	**State**	**Zip**
620 Shadow Lane	Las Vegas	NV	89106
Phone	**Title**		
702-388-7805	Assistant Director of Pharmacy		
Description of Duties			
Clinical staff Pharmacist and Assistant Director duties			

Business Name			From - To (MM/YY – MM/YY)
Post Medical Acute Rehab (PAM)			01/2018-07/2019
Business Address	**City**	**State**	**Zip**
6166 N Durango	Las Vegas	NV	89149
Phone	**Title**		
725-223-4100	Pharmacist		
Description of Duties			
Worked as needed to relieve other pharmacists. In patient pharmacist duties.			

Business Name			From - To (MM/YY – MM/YY)
Desert Parkway Behavior Health			12/2013-11/2015
Business Address	**City**	**State**	**Zip**
3247 S Maryland Parkway	Las Vegas	NV	89109
Phone	**Title**		
877-663-7976	Pharmacist I - PRN		
Description of Duties			
Worked as needed to relieve other pharmacists. In patient pharmacist duties.			

Business Name			From - To (MM/YY – MM/YY)
St John's Hospital			05/2000-06/2012
Business Address	**City**	**State**	**Zip**
800 East Carpenter	Springfield	IL	62769
Phone	**Title**		
217-544-6464	Pharmacist		
Description of Duties			
Clinical Staff Pharmacist, Facilitator of Research and Development, Instructor at St John's School of Nursing and Operations Manager/Assistant Director of Pharmacy			

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

Applicant's Initials

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

Applicant's initials JWR

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's Initials

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

Jennifer M Rogers

Print Name (First, Last)

Jennifer M Rogers

Original Signature (electronic, copies or stamps not accepted)

6/1/2021

Date

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

State of Nevada, ss. County of Clark

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

Jennifer M Rogers

Original Signature

6/1/2021

Date

Subscribed and Sworn to before me this 1st day of June 2021

Janice Marie Schwab

Notary Public Signature

JANICE MARIE SCHWAB
Notary Public, State of Nevada
Appointment No. 14-12761-1
My Appt. Expires Feb 20, 2022

(Seal)

Applicant's initials JMR

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VALLEY HEALTH SYSTEM LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF JUNE, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VALLEY HEALTH SYSTEM LLC" WAS FORMED ON THE SIXTEENTH DAY OF JANUARY, A.D. 1998.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2847793 8300

SR# 20205453828

Authentication: 203035072

Date: 06-02-20

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings & Notary Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

Work Order #: W2020120300311
December 3, 2020
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 40412

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Annual List	Fees	20201079791	12/3/2020 8:48:09 AM	Approved	1	$150.00	$150.00
Annual List	Business License Fee	20201079791	12/3/2020 8:48:09 AM	Approved	1	$200.00	$200.00
Total							$350.00

Payments

Type	Description	Payment Status	Amount
Credit Card	6070140773476663803017	Success	$350.00
Total			$350.00

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

12/03/2020

Work Order Item Number:	W2020120300311 - 977543
Filing Number:	20201079791
Filing Type:	Annual List
Filing Date/Time:	12/03/2020 08:48:09 AM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: LLC295-1998

Entity Name: VALLEY HEALTH SYSTEM LLC

Entity Status: Active

Expiration Date: 01/21/2498

Commercial Registered Agent
CORPORATION SERVICE COMPANY
112 NORTH CURRY STREET, Carson City, NV 89703, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☑ ANNUAL ☐ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

VALLEY HEALTH SYSTEM LLC	NV19981003340
NAME OF ENTITY	Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
Barbara K. Cegavske	LLC295-1998
	Filing Number
	20201079791
Secretary of State	Filed On
State Of Nevada	12/03/2020 08:48:09 AM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☐ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE MANAGING MEMBER:

Name	Country
VALLEY HOSPITAL MEDICAL CENTER INC	

Address	City	State	Zip/Postal Code
367 SOUTH GULPH ROAD	KING OF PRUSSIA	PA	19406-0958

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Steve Filton
Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Title	Date
Authorized Signer	12/03/2020

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

VALLEY HEALTH SYSTEM LLC

Nevada Business Identification # NV19981003340
Expiration Date: 01/31/2022

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/03/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202012031253601
You may verify this certificate online at http://www.nvsos.gov

Delaware

The First State

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED ARE TRUE AND CORRECT COPIES OF ALL DOCUMENTS ON FILE OF "VALLEY HEALTH SYSTEM LLC" AS RECEIVED AND FILED IN THIS OFFICE.

THE FOLLOWING DOCUMENTS HAVE BEEN CERTIFIED:

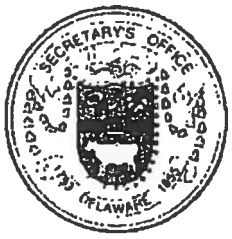
CERTIFICATE OF FORMATION, FILED THE SIXTEENTH DAY OF JANUARY, A.D. 1998, AT 4:30 O'CLOCK P.M.

CERTIFICATE OF MERGER, FILED THE THIRTIETH DAY OF JANUARY, A.D. 1998, AT 5 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE AFORESAID CERTIFICATES ARE THE ONLY CERTIFICATES ON RECORD OF THE AFORESAID LIMITED LIABILITY COMPANY, "VALLEY HEALTH SYSTEM LLC".

2847793 8100H

070874331



Harriet Smith Windsor

Harriet Smith Windsor, Secretary of State

AUTHENTICATION: 5890016

DATE: 07-31-07

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 04:30 PM 01/16/1998
981021061 - 2847793

CERTIFICATE OF FORMATION

OF

VALLEY HEALTH SYSTEM LLC

The undersigned, an authorized person, for the purpose of forming a limited liability company under the provisions of the Delaware Limited Liability Company Act, hereby certifies that:

FIRST: The name of the limited liability company is **VALLEY HEALTH SYSTEM LLC.**

SECOND: The address of the registered office and the name and the address of the registered agent of the limited liability company are The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

Executed on January 16, 1998.

Curtis Capeling, Organizer

125183 - 1

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 05:00 PM 01/30/1998
981039449 - 2847793

CERTIFICATE OF MERGER

OF

NEWCO Q LLC
(a Delaware limited liability company)

INTO

VALLEY HEALTH SYSTEM LLC
(a Delaware limited liability company)

IT IS HEREBY CERTIFIED THAT:

1. The constituent business entities participating in the merger herein certified are:

   (i) NEWCO Q LLC, a limited liability company formed under the laws of the State of Delaware; and

   (ii) VALLEY HEALTH SYSTEM LLC, a limited liability company formed under the laws of the State of Delaware.

2. An agreement of merger has been approved and executed by each of the above constituent entities in accordance with Section 18-209 of the Delaware Limited Liability Company Act.

3. The name of the surviving limited liability company in the merger herein certified is **Valley Health System LLC**, which will continue its existence as the surviving limited liability company under its present name upon the effective date of this merger.

4. The Certificate of Formation of Valley Health System LLC, as now in force and effect, shall continue to be the Certificate of Formation of the surviving limited liability company.

5. The executed agreement of merger between the aforesaid constituent entities is on file at the following place of business of the surviving limited liability company: 620 Shadow Lane, Las Vegas, Nevada 89106.

6. A copy of the agreement of merger will be furnished by the surviving limited liability company, on request and without cost, to any member of the constituent limited liability companies.

7. The merger shall be effective as of 12:01 a.m., Pacific time, February 1, 1998.

Executed on this 29th day of January, 1998.

VALLEY HEALTH SYSTEM LLC
By: Valley Hospital Medical Center, Inc.,
Sole Member

By: Steve Filton
Steve Filton, Vice President

Officers and Directors of Valley Hospital Medical Center, Inc.
Sole Member of Valley Health System, LLC

Name	Title	Corporate Address
Marvin Pember	President & Director	367 South Gulph Road King of Prussia, PA 19406
Steve Filton	Vice President & Director	367 South Gulph Road King of Prussia, PA 19406
Matthew D. Klein	Vice President, Secretary & Director	367 South Gulph Road King of Prussia, PA 19406
George H. Brunner, Jr.	Assistant Secretary	367 South Gulph Road King of Prussia, PA 19406
Cheryl K. Ramagano	Treasurer	367 South Gulph Road King of Prussia, PA 19406
Robert M. Zurad	Assistant Treasurer	367 South Gulph Road King of Prussia, PA 19406

URL Isolation https://download.intralinkscontent.com/services/workspaces/documents/file/Pharmacy%20License.pdf?client=DT-WEB&workspaceId=10699975&documentId=16369947388&forceDownload=T&csfToken=9Hwx2rrwZ8zEkWQDMnPs75DIJUh%ev...

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)
THIS STUB IS YOUR RECEIPT

Date: 09/28/2020
Amount: $ 525.00
Permit #: IB03894

ELITE MEDICAL CENTER
150 E HARMON AVE
LAS VEGAS NV 89109

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacy
Expires:10/31/2022
ELITE MEDICAL CENTER
150 E HARMON AVE
LAS VEGAS NV 89109

Permit #
IB03894
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY

Pharmacy

Expires: 10/31/2022
STATUS: Active

Permit Type: Pharmacy
Permit #: IB03894
Managing Pharmacist : STEVEN MCNUTT

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

ELITE MEDICAL CENTER
150 E HARMON AVE
LAS VEGAS NV 89109

NONTRANSFERABLE
POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

1894

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Elite Medical Center, An extension of Valley Hospital

Physical Address: 150 E. Harmon Avenue

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Jennifer Middle: Mary Last: Rogers

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

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

Mailing Address: [redacted]Yellow Shadow Ave

City: Las Vegas State: NV Zip: 89149

Telephone: [redacted] Email: [redacted]

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

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

Date of Service: From: 04/16/1975 to: 04/27/1978

Military Occupation/Specialty:

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ■ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials: JM

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

School Name		From - To (MM/YY – MM/YY)	
Midwestern University Chicago School of Pharmacy		08/2005-05/2008	
Address	**City**	**State**	**Zip**
555 31st Street	Downers Grove	IL	60515
Diploma/Degree obtained, if any			
Doctor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Midwestern University Chicago School of Pharmacy		09/1997-08/2020	
Address	**City**	**State**	**Zip**
555 31st Street	Downers Grove	IL	60515
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Lincoln Land Community College		1997	
Address	**City**	**State**	**Zip**
5250 Shepherd Road	Springfield	IL	62703
Diploma/Degree obtained, if any			
Associate Degree in Science			
School Name		**From - To (MM/YY – MM/YY)**	
Sacred Heart-Griffin High School (Sacred Heart Academy)		1968-1972	
Address	**City**	**State**	**Zip**
1200 West Washington	Springfield	IL	62702
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2016-present	[redacted]Yellow Shadow Ave	Las Vegas	NV	89149
03/2012-03/2016	1901 Bradbury Circle	Las Vegas	NV	89129
11/1988-03/2012	2404 South College	Springfield	IL	62704

Applicant's initials _____ 3

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Valley Hospital Medical Center			07/2012-present	
Business Address		**City**	**State**	**Zip**
620 Shadow Lane		Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**	
702-388-7805	Assistant Director of Pharmacy		greater than 16,000	

Description of Duties

Clinical Staff Pharmacist In-Patient duties and Assistant Director duties.

Business Name			From - To (MM/YY – MM/YY)	
Post Medical Acute Rehab (PAM)			01/2018-07/2019	
Business Address		**City**	**State**	**Zip**
6166 N Durango		Las Vegas	NV	89149
Phone	**Title**		**Number of Employed Hours**	
725-223-4100	Pharmacist			

Description of Duties

Worked as needed to relieve pharmacist. In-patient pharmacist duties.

Business Name			From - To (MM/YY – MM/YY)	
Desert Parkway Behavior Health			12/2013-11/2015	
Business Address		**City**	**State**	**Zip**
3247 S Maryland Parkway		Las Vegas	NV	89109
Phone	**Title**		**Number of Employed Hours**	
877-663-7976	Pharmacist I - PRN			

Description of Duties

Worked as needed to relieve pharmacist. In-patient pharmacist duties.

Business Name			From - To (MM/YY – MM/YY)	
St John's Hospital			05/2000-06/2012	
Business Address		**City**	**State**	**Zip**
800 East Carpenter		Springfield	IL	62769
Phone	**Title**		**Number of Employed Hours**	
217-544-6464	Pharmacist			

Description of Duties

Clinical Staff Pharmacist, Facilitator of Research and Development, Instructor at St John's School of Nursing and Operations Manager/Assistant Director of Pharmacy.

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

Description of Duties

Continue on next page if additional space is needed.

Applicant's Initials JMR

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

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

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

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

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

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

Applicant's Initials JMR

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's Initials

I, Jennifer M Rogers, certify that as the designated representative for Elite Medical Center, An extension of Valley Hospital Medical Center,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Jennifer M Rogers

Print Name (First, Last)

Jennifer M Rogers

Original Signature (electronic, copies or stamps not accepted)

6/1/2021

Date

Applicant's initials JMR

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

Jennifer M Rogers

Print Name (First, Last)

Jennifer M Rogers

Original Signature (electronic, copies or stamps not accepted)

6/1/2021

Date

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

State of Nevada, ss. County of Clark

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

Jennifer M Rogers

Original Signature

6/1/2021

Date

Subscribed and Sworn to before me this 1st day of June, 2021

Janice Marie Schwab

Notary Public Signature

JANICE MARIE SCHWAB
Notary Public, State of Nevada
Appointment No. 14-12761-1
My Appt. Expires Feb 20, 2022

(Seal)

Applicant's initials JMR

9D

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ Ownership Change (Provide current license number if making changes: PH_____

Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☒ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Genoa Healthcare, LLC

Physical Address: 701 Shadow Lane

City: Las Vegas State: Zip Code: 89106 Telephone: Pending

Fax: Pending Toll Free Number: 1-888-410-8746

E-mail: licensecoordinator@genoahealthcare.com

Website: www.genoahealthcare.com

Managing Pharmacist: Kyle Folk License Number: 18571

TYPE OF PHARMACY AND		SERVICES PROVIDED	
Yes/No		Yes/No	
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☒	☐ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☒	☐ Mail Service
☒	☐ Community	☒	☐ Long Term Care
☐	☒ Other: _____	☐	☒ Sterile Compounding
		☐	☒ Non Sterile Compounding
All boxes must be checked		☐	☒ Mail Service Sterile Compounding
For the application to be complete		☐	☒ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Joseph Douglas
Print Name of Authorized Person

5/24/21
Date

Board Use Only	Date Processed:	Amount: 500 Check: 0002061513

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Pennsylvania

Parent Company if any: Specialized Pharmaceuticals, Inc

Mailing Address: 707 S Grady Way, Suite 700

City: Renton State: WA Zip: 98057

Telephone: 253-218-0830 Fax: 253-217-4306

Contact Person: Joseph Douglas - CEO

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. 100%

3) What was the price paid per share? N/A

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5:30 pm

Saturday Closed am on-Call pm

Sunday Closed am on-call pm

24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: Pending

Include with the application for a non publicly traded corporation continued

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Joseph Douglas

Responsible Person of Genoa Healthcare, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Joseph Douglas - CEO
Print Name of Authorized Person

5/24/21
Date

Managing Pharmacist

Pharmacist Name: Kyle Folk License #: 18571

Pharmacy Name: Genoa Healthcare, LLC

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	■
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	■
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	■
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	■

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____
County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature

5/24/21
Date

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Genoa Healthcare, LLC

Physical Address 701 Shadow Lane, Suite 110

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) 8441 Wayzata Blvd, Suite 340

City Golden Valley State MN Zip 55426

Telephone 253-218-0830 Website www.genoahealthcare.com

Licensing Company Email licensecoordinator@genoahealthcare.com

Section 2: Personal Information

First Specialized Pharmaceuticals, Inc Middle _____ Last _____

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

Date of Birth 5/26/2000 SSN or ITIN 25-1868213 Sex ☐ M ☐ F ☒ X

Mailing Address 707 S Grady Way, Suite 700

City Renton State WA Zip 98057

Telephone 253-218-0830 Email licensecoordinator@genoahealthcare.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials _____

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials

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

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

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

Applicant's initials _____

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

Applicant's initials _____

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

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/19/2013	12/15/2014	IL	Rockford	Winnebago

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2013-01026	State of Illinois Department of Financial and Professional Regulation

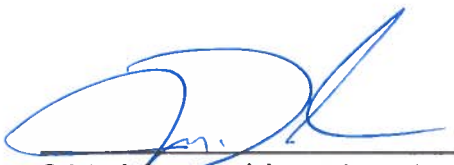
Reason/Charge	
See Below	

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Division of Professional Regulation v. QoL Meds, LLC	Consent Order

Name of Business/Industry/Entity
QoL Meds, LLC

Provide explanation below:

Disciplinary action alleging that a QoL Meds pharmacy in Rockford, IL violated the Illinois Pharmacy Practice Act. All alleged activities took place in February 2013, 17 months prior to the pharmacy being acquired by Genoa Healthcare in July 2014. The Consent entered in October 2014 alleges that the QoL Meds pharmacy (1) dispensed medications without a pharmacist on duty, (2) dispensed medications from an unlicensed pharmacy location, (3) dispensed controlled substances before the authorized refill date, (4) mislabeled drug vials, (5) maintained expired medications in active stock, and (6) charge a third party dispensing fee for free drug samples. A corrective action plan was submitted in October 2014, quarterly onsite audits are conducted, and a fine of $20,000 was paid. Since instituting the corrective action plan in 2014, the pharmacy has operated in compliance with all laws. The pharmacy's Illinois pharmacy license was restored and probation was lifted on February 18, 2020.



Original Signature (electronic, copies or stamps not accepted)

5/24/21

Date

Applicant's initials



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

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/31/2017	7/30/2018	OR	Salem	Salem

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2017-0523	Oregon State Board of Pharmacy

Reason/Charge
See Below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Oregon State Board of Pharmacy v. GenoaHealthcare, LLC	Consent Order

Name of Business/Industry/Entity
Genoa Healthcare, LLC

Provide explanation below:

Disciplinary action alleging an apparent failure to have a PIC at the Salem, OR pharmacy site for a period of six weeks in 2017. Although the site did have a PIC in place at all times, a requisite form documenting a change in PIC was not timely filed by the temporary PIC, creating a gap in Board of Pharmacy online filings. A Consent Order was received by the Oregon Board of Pharmacy on July 30, 2018 and $6,000 fine was paid.

Original Signature (electronic, copies or stamps not accepted)

5/24/21
Date

Applicant's initials

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

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/5/2018	4/11/2019	AZ	Gilbert	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
18-0080	Arizona State Board of Pharmacy

Reason/Charge
See Below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Arizona State Board of Pharmacy v. Genoa Healthcare, LLC	Consent Agreement

Name of Business/Industry/Entity
Genoa Healthcare, LLC

Provide explanation below:

Disciplinary action alleging a failure of not complying with the Arizona state regulations regarding "shared" after-hours pharmacy service following a routine pharmacy inspection on March 5, 2018. In particular, the appropriate notice to customers as to the after-hours pharmacy service Genoa was using there was not sufficient policies and procedures regarding such service. There was no allegation that patient care was impacted. A new after-hours vendor was put in place and we have educated our pharmacies to ensure that patients are aware that their after-hour needs are being met by another pharmacy service that has compliant policies and procedures regarding "shared services". A Consent Order was received by the Arizona State Board of Pharmacy in March 2019 and a $500 fine was paid.

Original Signature (electronic, copies or stamps not accepted)

5/24/21
Date

Applicant's initials

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

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/9/2019	4/20/2020	GA	Rome	Floyd

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2020-0038	Georgia State Board of Pharmacy

Reason/Charge
See Below

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Georgia Board of Pharmacy v. Genoa Healthcare, LLC	Consent Order

Name of Business/Industry/Entity
Genoa Healthcare, LLC

Provide explanation below:

Disciplinary action against a technician employed at the pharmacy for failure of not complying with Georgia state regulations regarding diversion of medications. A consent order was received from the Georgia Board of Pharmacy on April 20, 2020 and a $4,060 fine was paid.



Original Signature (electronic, copies or stamps not accepted)

5/24/21

Date

Applicant's initials



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

Joe Douglas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/24/21

Date

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

State of Minnesota, ss. County of Hennepin

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

Original Signature

5/24/21

Date

Subscribed and Sworn to before me this 24 day of May 2021

Notary Public Signature

Amy M Halliday
Notary Public
Minnesota
My Commission Expires January 31, 2026

(Seal)

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Genoa Healthcare, LLC

Physical Address 701 Shadow Lane, Suite 110

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) 8441 Wayzata Blvd Suite 340

City Golden Valley State MN Zip 55426

Telephone 253-218-0830 Website www.genoahealthcare.com

Licensing Company Email licensecoordinator@genoahealthcare.com

Section 2: Personal Information

First Kyle Middle Richard Last Folk

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

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

Mailing Address 701 Shadow Lane, Suite 110

City Las Vegas State NV Zip 89106

Telephone [redacted] Email kfolk@genoahealthcare.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

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

Applicant's initials KF

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

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences		8/2010 - 6/2013	
Address	**City**	**State**	**Zip**
11 sunset way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada Las Vegas		9/2004 - 6/2008	
Address	**City**	**State**	**Zip**
4505 S maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
Bachelor of Science Biology			

School Name		From - To (MM/YY – MM/YY)	
Maui High School		9/2000 - 6/2004	
Address	**City**	**State**	**Zip**
660 Lono Ave	Kahului	HI	96732
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2016 - current	[redacted] Danzinger Place	Henderson	NV	89044
9/2005 - 10/2016	10972 scotch Rose St	Henderson	NV	89052
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials KPR

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
optum Specialty Pharmacy			6/2019 - current
Business Address	**City**	**State**	**Zip**
701 shadow Lane suite 110	Las Vegas	NV	89106
Phone	**Title**	**Number of Employed Hours**	
877-480-1755	Pharmacist in Charge	4160	
Description of Duties			
manage of pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
CVS Pharmacy			6/2013 - 6/2019
Business Address	**City**	**State**	**Zip**
2830 Bicentennial Parkway	Henderson	NV	89052
Phone	**Title**	**Number of Employed Hours**	
702-260-8419	Pharmacist in Charge	12,480	
Description of Duties			
manage of pharmacy operations			

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

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

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

Continue on next page if additional space is needed.

Applicant's initials KR

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

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

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

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

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

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

Applicant's initials BRC

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

Applicant's initials _____

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/24/21
Date

Applicant's initials _____

I, Kyle Richard Folk, **certify that as the designated representative for**

Genoa Healthcare, LLC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Kyle Folk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/24/21

Date

Applicant's initials KF

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

Kyle Folk

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/24/21

Date

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

State of Nevada, ss. County of Clark

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

Original Signature

5/24/21

Date

Subscribed and Sworn to before me this 24TH day of May 2021.

Notary Public Signature

DARLENE TACTACAN
Notary Public - State of Nevada
County of Clark
APPT. NO. 97-3665-1
My App. Expires Sept. 14, 2021

(Seal)

Applicant's initials KF

Genoa has been subject to the following Disciplinary Action:

Illinois Department of Financial & Professional Regulation (2014) – Rockford, Illinois (Case No 2013-01026): Disciplinary action alleging that a QoL Meds pharmacy in Rockford, IL violated the Illinois Pharmacy Practice Act. All alleged activities took place in February 2013, 17 months prior to the pharmacy being acquired by Genoa Healthcare in July 2014. The Consent entered in October 2014 alleges that the QoL Meds pharmacy (1) dispensed medications without a pharmacist on duty, (2) dispensed medications from an unlicensed pharmacy location, (3) dispensed controlled substances before the authorized refill date, (4) mislabeled drug vials, (5) maintained expired medications in active stock, and (6) charge a third party dispensing fee for free drug samples. A corrective action plan was submitted in October 2014, quarterly onsite audits are conducted, and a fine of $20,000 was paid. Since instituting the corrective action plan in 2014, the pharmacy has operated in compliance with all laws. The pharmacy's Illinois pharmacy license was restored and probation was lifted on February 18, 2020.

Oregon Board of Pharmacy (2018) – Salem, Oregon (Case No. 2017-0523): Disciplinary action alleging an apparent failure to have a PIC at the Salem, OR pharmacy site for a period of six weeks in 2017. Although the site did have a PIC in place at all times, a requisite form documenting a change in PIC was not timely filed by the temporary PIC, creating a gap in Board of Pharmacy online filings. A Consent Order was received by the Oregon Board of Pharmacy on July 30, 2018 and $6,000 fine was paid.

Arizona State Board of Pharmacy (2019) – Gilbert, Arizona (Case No. 2018-0080): Disciplinary action alleging a failure of not complying with the Arizona state regulations regarding "shared" after-hours pharmacy service following a routine pharmacy inspection on March 5, 2018. In particular, the appropriate notice to customers as to the after-hours pharmacy service Genoa was using there was not sufficient policies and procedures regarding such service. There was no allegation that patient care was impacted. A new after-hours vendor was put in place and we have educated our pharmacies to ensure that patients are aware that their after-hour needs are being met by another pharmacy service that has compliant policies and procedures regarding "shared services". A Consent Order was received by the Arizona State Board of Pharmacy in March 2019 and a $500 fine was paid.

Georgia Board of Pharmacy (2020)—Rome, Georgia (Case No. 2020-0038): Disciplinary action against a technician employed at the pharmacy for failure of not complying with Georgia state regulations regarding diversion of medications. A consent order was received from the Georgia Board of Pharmacy on April 20, 2020 and a $4,060 fine was paid.

QoL meds, LLC

12/15/14

To: State of Illinois
Department of Financial and Professional Regulation

Re: Case #2013-01026 QoL meds, LLC - License No. 054.018414
Corrective Action Plan

Response to A2: All sample medications have been removed from the pharmacy and the employees will not order, accept, store, transfer, or dispense sample medication of any kind during the 5 year probationary period.

Response to A4: A check for the amount $20,000.00 has been sent to Illinois Department of Financial and Professional Regulation Attn: Fiscal Section as required.

Response to B: QoL meds, LLC shall provide a quarterly compliance report to the Department for the duration of the probation. A Compliance Auditor shall inspect the pharmacy on a quarterly basis and provide the written report to the Department. The Auditor will use the Illinois Pharmacy Self-Inspect report as a guideline.

Response to E: All copies of licensure have been sent to the Department and have been returned stamped "Probation" and are displayed in the pharmacy.

Sincerely,

Christy Barr, RPh
Director of Operations

Corporate Offices: 4900 Perry Highway Building II Pittsburgh, Pennsylvania 15229
Telephone: 866-401-6337 Facsimile: 412-931-2361
Web Address: www.qolmeds.com

DO NOT CASH IF THIS DOCUMENT DOES NOT HAVE A LARGE PAINT IMAGE OF THE SECURE DOCUMENT SHIELD OVER A FADING PATTERN OF THE WORDS "SECURE DOCUMENT"

GENOA, A QOL HEALTHCARE COMPANY
18300 CASCADE AVE S SUITE 251
TUKWILA, WA 98188
(253) 218-0830

Wells Fargo Bank, N.A

60497
11-24/7210

PAY TO THE ORDER OF Illinois Dept of Financial & Professional Regulation 12/19/2014 $ 20,000.00

Twenty Thousand Dollars and 00 Cents DOLLARS

AUTHORIZED SIGNATURE

Illinois Dept of Financial & Professional Regulati
ATTN: Fiscal Section
MEMO 320 W Washington, 3rd Fl
Springfield IL 62786

⑈60497⑈ ⑆121000248⑆ 4088256375⑈

GENOA, A QOL HEALTHCARE COMPANY

Vendor ID	Name	Account Number	Check Date	Document Number
000749	Illinois Dept of Financial & Profe		12/19/2014	60497

Date	Reference	Amount	Amount Paid	Discount	Payment
12/18/2014	CR121814-10812	20,000.00	20,000.00	0.00	20,000.00
		20,000.00	20,000.00	0.00	20,000.00

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION of the State of Illinois, Complainant	)	
v.	)	201301026
QOL MEDS, LLC Respondent	)	

NOTICE

TO: QOL MEDS, LLC
526 W. STATE STREET
ROOM 302
ROCKFORD, IL 61101-1214

PLEASE TAKE NOTICE that the Director of the Division of Professional Regulation did sign the attached Consent Order.

The Order of the Director of the Division of Professional Regulation will be implemented as of the date of the Order unless the Order states otherwise.

DIVISION OF PROFESSIONAL REGULATION
of the State of Illinois

BY: _____
Clerk for the Department

All inquiries should be
Directed to:
Chicago Office - 312-814-4504
Unless Downstate Parcs - 217-782-8464

STATE OF ILLINOIS)
) ss:
COUNTY OF SANGAMON)

UNDER PENALTY of perjury, as provided by law pursuant to Section 1-109 of the Illinois Code of Civil Procedure, the undersigned Certifies that I caused copies of the attached NOTICE AND CONSENT OR ORDER, to be deposited in the United States mail, by certified mail at 320 W. Washington, Springfield, Illinois 62786, before 5:00 p.m. with proper postage prepaid on the 29th day of October, 2014 to all parties at the addresses listed on the attached documents.

Heidi Bondy

AFFIANT

STATE OF ILLINOIS
ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, DIVISION OF PROFESSIONAL REGULATION of the State of Illinois,	Complainant	
v.		No. 2013-01026
QOL MEDS, LLC License No. 054.018414,	Respondent.	

CONSENT ORDER

The Illinois Department of Financial and Professional Regulation, Division of Professional Regulation (hereinafter the "Department") by Bill Laskaris, its Chief of Health Related Prosecutions, and QOL MEDS, LLC., Respondent, through Anthony Calamunci, its attorney, hereby agree to the following:

STIPULATIONS

QOL MEDS, LLC. is a licensed pharmacy in the State of Illinois, holding License No. 054.081414. Said license is presently in active status. At all times material to the matters set forth in this Consent Order, the Illinois Department of Financial and Professional Regulation of the State of Illinois had jurisdiction over the subject matter and parties to this Consent Order.

A pharmacy inspection performed on February 19, 2013 revealed that employees at QOL Meds, LLC. violated several provisions of the Illinois Pharmacy Practice Act, including: (1) Dispensing medications without a pharmacist on duty; (2) dispensing medications from an unlicensed pharmacy location; (3) dispensing Schedule II medications before the authorized dispense date; (4) mislabeling prescription drug vials by listing a pharmacy technician as the dispensing pharmacist; (5) maintaining expired and unlabeled medications in active stock; and (6) charging a 3rd party dispensing fee for free drug samples. Respondent had not previously been disciplined.

The Illinois Pharmacy Act, 225 ILCS 85/30 states, in part, the following:

(a) The Department may refuse to issue or renew, or may revoke a license or registration, or may suspend, place on probation, fine, or take any disciplinary or non-disciplinary action as the Department may deem proper, including fines not to exceed $10,000 for

each violation, with regard to any license or registrant for any one or combination of the following causes:

7. Engaging in unprofessional, dishonorable, or unethical conduct of a character likely to deceive, defraud, or harm the public.

11. Selling or engaging in the sale of drug samples provided at no cost by drug manufacturers.

The aforementioned conduct as set forth herein, if proven to be true, would constitute grounds for disciplinary action against Respondent's license as a pharmacy on the authority of 225 ILCS 85/30(a)(7); 225 ILCS 85/30(a)(11); 68 Ill. Admin. Code § 1330.40(a)(2) (2010).

As a result of these allegations, the Department held an Informal Disciplinary Conference at the offices of the Department, 100 West Randolph Street, Suite 9-300, in Chicago, Illinois, on April 17, 2014. Respondent QOL MEDS, LLC. was represented by counsel, Anthony Calamunci., Esq. Yash Patel, R.Ph., appeared as a member of the Illinois State Board of Pharmacy, Patrick J. Reda appeared as the attorney for the Department, and Anita Patel, PharmD. appeared as 711 Law Clerk for the Department.

Respondent has been advised of the right to have the pending allegation reduced to written charges, the right to a hearing, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation. Respondent acknowledges that they have entered into this Consent Order freely and of her own will without threat or coercion by the Department or any person. Respondent acknowledges that the Department attorney may be requested to communicate with the Illinois State Board of Pharmacy or the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation in furtherance of the approval of this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department, providing for the imposition of Consent

measures which are fair and equitable under the circumstances and which are consistent with the best interests of the people of the State of Illinois.

TERMS AND CONDITIONS

WHEREFORE, the Department, through Bill Laskaris, its Chief of Health Related Prosecutions, and QOL MEDS, LLC., Respondent, through Anthony Calamunci, its attorney, agree on the following Terms and Conditions:

A. The Pharmacy license of QOL MEDS, LLC., License No. 054.018414, shall immediately be placed on INDEFINITE PROBATION. Applicant cannot petition to restore its pharmacy license for at least five (5) years from the effective date of this Consent Order. During the period of probation, Applicant shall be subject to the following:

1. Respondent shall furnish the Department with a corrective action plan no later than ninety (90) days of the effective date of this Consent Order.
2. Respondent and its employees cannot order, accept, store, transfer, or dispense sample medications of any kind during the probation period.
3. **Respondent understands and expressly agrees that evidence of any violation of paragraphs A1 or A2 of this Consent Order or repeated violations of the remaining paragraphs of this Consent Order shall result in the Department's automatic, indefinite, and immediate suspension of Respondent's Pharmacy License, No. 054.018414, for a minimum period of twelve (12) months. Respondent knowingly waives all rights to and associated with Notice and a Formal Hearing under these circumstances. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate, which may include taking action to revoke Petitioner's license to practice as a pharmacy.** In the event Respondent contests in writing by the filing with the Department within fifteen (15) days of the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings), the factual basis underlying said suspension, then Respondent shall be afforded a Hearing on the merits.

4. QOL MEDS, LLC., holder of Pharmacy License No. 054.018414, shall pay a fine of twenty thousand dollars ($20,000.00) within ninety (90) days of the effective date of this Order. The fine is to be paid by personal check, cashier's check, or personal money order. Said check shall be made payable to:

   Illinois Department of Financial and Professional Regulation
   Attention: Fiscal Section
   320 W. Washington, 3rd floor
   Springfield, IL 62786

   In the notation portion of the check, this case No. 2013-01026 and License No. 054.018414 shall be reflected.

5. **In the event the fine of twenty thousand dollars ($20,000.00) is not paid to the Department, within ninety (90) days of the effective date of this Consent Order, Respondent acknowledges and agrees that its failure to pay the full amount of the fine will permit the Director of the Division of Professional Regulation to issue an Order forthwith mandating the automatic, indefinite and immediate suspension of Respondent's Pharmacy License, No. 054.018414. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. This suspension shall remain in full force and effect until such time as the Department receives the full amount of the fine of twenty thousand dollars ($20,000.00). In the event Respondent contests in writing the factual basis underlying said suspension and does so within thirty (30) days of the imposition of the automatic suspension, Respondent shall be afforded a hearing on the merits.**

6. If Respondents fail to pay the aforementioned fine, or any portion of the fine, and the Department initiates a collection effort to retrieve the fine, or any portion of the fine, Respondents shall be responsible for all costs and fees incurred by the Department in said collection effort.

B. Respondent shall report to the Department quarterly compliance with this Consent Order.

C. Any violation(s) by Respondent of the terms and/or conditions of this Consent Order shall be grounds for the Department to immediately file a Complaint to revoke or otherwise discipline Respondent's license to practice as a pharmacy in the State of Illinois.

D. Any violation(s) by Respondent of the Illinois Pharmacy Practice Act and/or the Rules for the Administration of the Illinois Pharmacy Practice Act during the period of probation shall constitute a violation of probation and shall be grounds for the Department to immediately file a Complaint to revoke or otherwise discipline Respondent's license to practice as a pharmacist in the State of Illinois.

E. Respondent shall send to the Department all indicia of licensure, including all copies of wall certificates and wallet cards. The certificates of licensure shall be stamped "Probation" and returned to Respondent. Respondent shall send said certificates of licensure to:

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Attn: Probation Compliance Unit
9511 Harrison Street, Suite LL50
Des Plaines, Illinois 60016

F. All reports required to be submitted to the Department pursuant to this Consent Order shall be sent to:

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Attn: Probation Compliance Unit
9511 Harrison Street, Suite LL50
Des Plaines, Illinois 60016

G. This Consent Order shall become effective immediately upon signing and approval by the Director of the Division of Professional Regulation of the Department.

DIVISION OF PROFESSIONAL REGULATION
of the State of Illinois

10-21-14
DATE

Bill Laskaris
Chief of Health Related Prosecution

10/1/2014
DATE

QOL MEDS, LLC.
by its designated representative, Respondent

10/10/2014
DATE

Anthony Calamunci
Attorney for Respondent

10/10/14
DATE

Yash Patel
Illinois State Board of Pharmacy

THIS CONSENT ORDER IS APPROVED IN FULL:

DATED THIS 23rd DAY OF October, 2014.

ILLINOIS DEPARTMENT OF FINANCIAL AND
PROFESSIONAL REGULATION
OF THE STATE OF ILLINOIS
MANUEL FLORES, ACTING SECRETARY
DIVISION OF PROFESSIONAL REGULATION

JAY STEWART
DIRECTOR

Case No.: 2013-01026
License No.: 054.018414

Arizona State Board of Pharmacy
Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749 www.azpharmacy.gov

April 11, 2019

Genoa Healthcare, LLC
Attn: Ms. Kathleen McGuan
18300 Cascade Ave S Suite 251
Tukwila, WA 98188

Re: Consent Agreement for Civil Penalty – Board Case No. 18-0080

Dear Ms. McGuan,

Please find enclosed a copy of the Consent Agreement for Civil Penalty in Board Case No. 18-0080. After the Consent Agreement was signed, staff discovered a typographical error. Specifically, the permit number on page 1, line 13 was incorrect. Staff corrected the error and replaced page 1 of the document. The corrected permit number was the only change made to the document.

If you have any questions regarding this matter, please contact this office.

Sincerely,

Kamlesh Gandhi
Executive Director

KG/jcm

Enclosure



MARK BRNOVICH
Attorney General
(Firm State Bar No. 14000)

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
2005 North Central Ave. SGD/LES
Phoenix, Arizona 85004
Tel: (602) 542-7983
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of	
	Board Case No. 18-0080
Genoa Healthcare,LLC, #20120,	**CONSENT AGREEMENT FOR CIVIL PENALTY**
Permit No. Y007067 As a Licensed Pharmacy In the State of Arizona	

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Genoa Healthcare, LLC, #20120 ("Respondent"), holder of permit no. Y007067 as a licensed pharmacy in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Respondent has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Respondent understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Respondent knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Respondent understands this Consent Agreement deals with Board Complaint No. 18-0080 involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

8. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke acceptance of the Consent Agreement or make any modifications to the document regardless of whether the Consent Agreement has been signed by the Executive Director. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Respondent shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(19) and A.R.S. §32 – 1927.02(A) (1).

13. Respondent agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY RESPONDENT

Dated: 3/27/19

On Behalf of
Genoa Healthcare, LLC,
Permit Holder NO. Y007067

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Respondent is Genoa Healthcare, LLC, #20120, holder of permit no. Y007067, to operate as a pharmacy in the State of Arizona. At all relevant times, Respondent was located at 5222 East Baseline Rd, Gilbert, AZ 85234.

3. On or about March 5, 2018, Board staff conducted a routine inspection of Respondent's premise. In response to staff's question about delivery services, Respondent's PIC, Mr. Kyle Clonts, responded that Genoa Healthcare, LLC, #20120 utilized Medcall to answer after-hours patient questions, noting that Medcall had access to patient profiles. In addition, it was revealed that Medcall was able to transfer prescriptions for patients after hours from Genoa to the pharmacy of choice.

4. At the time of inspection, the PIC was unable to produce the shared services agreement with Medcall or the Respondent's policies and procedures relating to shared services.

5. Subsequent to the investigation, the Respondent provided what it believed to be the appropriate shared services agreement, however, upon further review it was determined that the contract with Medcall listed only two Genoa Arizona locations.

6. Additionally, the permit on file with the Board is Y004817 and belongs to Homemed. There is no permit for Medcall that would allow it to conduct pharmacy business in the State of Arizona.

7. Subsequent to the inspection, Respondent notified the Board that it has discontinued using Medcall to ensure compliance with Arizona regulations.

CONCLUSIONS OF LAW

1. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1901 *et seq*.

2. The Board may discipline a permittee who has engaged in unprofessional conduct. A.R.S. § 32-1927.02(A) (1).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(5) as it relates to Arizona Administrative Code R4-23-621(A), (B)(2) and (C)(a) and (b).

ORDER

Based upon the above Findings of Fact and Conclusions of Law, IT IS HEREBY ORDERED THAT:

1. Respondent shall pay to the Board as a civil penalty the sum of **$500.00 for not having complied with shared services regulations by providing advance notice to patients that their orders would be filled by a shared service pharmacy and having adequate policies and procedures regarding shared services.** The civil penalty shall be paid in full to the Board within **ninety (90) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. If the Board determines that Respondent has not complied with **all** the requirements of this Consent Agreement, the Board, in its sole discretion, may institute proceedings for noncompliance with this Consent Agreement, which may result in the suspension or revocation of Respondent's permit. Failing to abide by this Consent Agreement and Order is a violation of A.R.S. §32-1901.01(A)(19), which is violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board it its executive director."

3. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

4. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, may revoke, suspend or take other disciplinary actions against Respondent's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 11th day of April, 2019.

ARIZONA STATE BOARD OF PHARMACY

(Seal)

By: _____
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FORGOING FILED
this 11th day of April, 2019, with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

EXECUTED COPY OF THE FOREGOING MAILED
BY CERTIFIED MAIL
this 11th day of April, 2019, to:

Genoa Healthcare, LLC
Attn: Ms. Kathleen McGuan
18300 Cascade Ave. S., Ste. 251
Tukwila, WA 98188

EXECUTED COPY OF THE FOREGOING MAILED
this 11th day of April, 2019, to:

Jeanne M. Galvin
Assistant Attorney General
2005 North Central Ave., SGD/LES
Phoenix, Arizona 85004
Attorneys for the Board

_____
Doc #7078160

RECEIVED
JUL 30 2018
OREGON BOARD OF PHARMACY

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2017-0523
GENOA HEALTHCARE, LLC	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits that while they did not have a pharmacist-in-charge registered with the Board as required during the timeframe in the Notice, they did have a pharmacist completing the responsibilities of a pharmacist-in-charge;

WHEREAS, the registrant admits that legal cause exists pursuant to ORS 689.405 and ORS 689.445 for disciplinary action and imposition of a civil penalty by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The registrant shall pay the Board a civil penalty in the amount of $6,000, said payment to be made within ten days from the date this Consent Order becomes final.

2. Failure of the registrant to pay the civil penalty as required under this Consent Order may, after notice and hearing, result in further disciplinary action.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

Kathleen McGowan — 1-27-2018

Authorized Representative — Date
GENOA Healthcare, LLC
Registrant (Reg. No. RP-0002461)

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Brianne Efremoff — 7/31/18

Brianne Efremoff, Pharm.D, R.Ph., — Date
Compliance Director

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2017-0523
GENOA HEALTHCARE, LLC	)	NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED
Registrant	)	

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. RP-0002461 because Genoa Healthcare, LLC violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

Genoa Healthcare, LLC, located at 3180 NE Center St Ste 3360 in Salem, OR did not have a pharmacist-in-charge from on or about June 10, 2017 through July 31, 2017, in violation of OAR 855-041-1010(1) and OAR 855-019-0300(1), which is grounds for discipline and imposition of a civil penalty pursuant to ORS 689.335(1), 689.405(1)(e)(B), 689.832(1) and 689.445(1)(d).

Based on these alleged violations, the Board proposes to impose a civil penalty in the amount of $1,000 per violation.

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the

Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

- (a) An admission or denial of each factual matter alleged in the notice;
- (b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause;

- (a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;
- (b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;
- (c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and
- (d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Brianne Efremoff, Pharm.D, R.Ph.,
Compliance Director

2/15/18
Date

DATE OF MAILING 2-16-2018

GEORGIA BOARD OF PHARMACY

GOVERNOR
Brian P. Kemp

EXECUTIVE DIRECTOR
Tanja D. Battle

2 Peachtree St. N.W., 6th Floor • Atlanta, Georgia 30303 • Tel: 404.651.8000 • Fax 470.386.6137
www.gbp.georgia.gov

April 20, 2020

Sent via Certified Mail:

Genoa Healthcare, LLC
3140 Neil Armstrong Blvd., Ste. 110
Eagan, MN 55121

Re: Public Consent Order

Dear Agent of Genoa Healthcare, LLC:

Please find enclosed a copy of Public Consent Order # 2020-0038 from the Georgia Board of Pharmacy. If you have any questions regarding this matter or any other matter related to the practice of pharmacy in Georgia, please contact the staff at the Board's office at your convenience: (404) 651-8000.

Sincerely,

Georgia State Board of Pharmacy

Enclosures

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
GENOA HEALTHCARE, LLC,	)	**DOCKET NO.**
License No. PHRE010169,	)	
	)	
Respondent.	)	

GEORGIA STATE BOARD OF PHARMACY
APR 20 2020
DOCKET NO. 2020-0038

PUBLIC CONSENT ORDER

By agreement of the Georgia State Board of Pharmacy ("Board") and Genoa Healthcare, LLC, Respondent, the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. § 50-13-13(a)(4).

FINDINGS OF FACT

1.

Respondent is licensed as a pharmacy in the State of Georgia. Respondent's license was issued August 19, 2015, and expires June 30, 2021.

2.

On or about May 9, 2019, the Georgia Drugs and Narcotics Agency initiated an investigation after a report of possible diversion at the Respondent pharmacy. The investigation revealed that the pharmacy had a loss of 1,660 tablets of amphetamine 20mg and 370 tablets of amphetamine 30mg from May 2017 until May 2019. Further investigation confirmed that the technician employed at the pharmacy diverted the tablets.

3.

Upon discovery of the possible diversion of controlled substances, Respondent promptly: (i) terminated the pharmacy technician and the Pharmacist in Charge (PIC); and (ii) reported the possible diversion to the Georgia Drugs and Narcotics Agency.

CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4 and T. 43, Ch. 1, the Georgia State Board of Pharmacy has authority to take action against the license of the Respondent. Respondent agrees that the Board can impose disciplinary action against the license of the Respondent and waives any further conclusions of law with respect to this matter.

ORDER

The Board having considered the particular facts and circumstances of this case, it is hereby ORDERED, and the Respondent hereby AGREES, that Respondent's license shall be disciplined as follows:

1.

The Respondent shall submit to the Board a fine in the amount of $4,060.00 for the diversion of controlled substances. Such fine shall be payable within sixty (60) days from the effective date of this Consent Order. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy and submitted to the Board at 2 Peachtree Street, N.W., 6th Floor, Atlanta, Georgia 30303. The Respondent's failure to pay such fine by the sixtieth day shall subject Respondent's license to further disciplinary action, up to and including revocation.

2.

This Consent Order and dissemination thereof shall also serve as a public reprimand to the Respondent.

3.

Approval of this Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning the Respondent's alleged conduct, and shall not be construed as a waiver of any of the lawful rights possessed by the Board. This Consent Order shall not become effective until approved and docketed by the Georgia State Board of Pharmacy.

4.

Agent of Respondent, Genoa Healthcare, LLC, acknowledges that Agent of Respondent has read this Consent Order and understands its contents. Respondent understands that Respondent has a right to a hearing in this matter, and Respondent freely, knowingly and voluntarily waives such right by entering into this Consent Order. Respondent understands that this Consent Order will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Consent Order. Respondent further understands that this Consent Order, once approved, shall constitute a public record of the Board. Respondent further understands that if this Consent Order is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

(Signatures on the following page)

This 15th day of April, 2020.

GEORGIA STATE BOARD OF PHARMACY

BY: Lisa C. Harris
LISA C. HARRIS, R.Ph.
President

with express permission by
Tanja Battle, Executive Director

(BOARD SEAL)

ATTEST: Tanja D. Battle
TANJA D. BATTLE
Executive Director

CONSENTED TO:

Richard Wade
AGENT,
ON BEHALF OF GENOA HEALTHCARE, LLC
Respondent

AS TO SIGNATURE OF AGENT ON BEHALF OF RESPONDENT
Sworn to and subscribed before me
this _____ day of _____, 20__.

_____
NOTARY PUBLIC
My commission expires:

genoa healthcare®

Officers and Director of the Board
FEIN: 27-0556097

Name	Title	Business Address and Phone	% Interest
Joseph Scott Douglas	CEO, Manager	707 S Grady Way Suite 700 Renton WA 98057 253-218-0830	0
Thomas Mullin	Manager	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0
Karen Elizabeth Peterson	Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0
Kirsten Colleen Hines	Assistant Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0
Heather Anastasia Lang	Assistant Secretary	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0
Peter Marshall Gill	Treasurer	9900 Bren Road East Minnetonka, MN 55343 952-936-1300	0

Officers have 0% ownership in Genoa Healthcare, LLC

Specialized Pharmaceuticals, Inc.

FEIN: 25-1868213

Address: 707 S. Grady Way, Suite 700, Renton, WA 98057 **Telephone Number:** (253) 218-0830

Parent of Genoa Healthcare LLC 100% Ownership



Genoa Healthcare LLC

FEIN: 27-0556097

Address: 707 S. Grady Way, Suite 700, Renton, WA 98057 **Telephone Number:** (253) 218-0830

Subsidiary of Specialized Pharmaceuticals, Inc. 0% Ownership

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

05/26/2021

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT,

Specialized Pharmaceuticals, Inc.

is duly registered as a Pennsylvania Business Corporation under the laws of the Commonwealth of Pennsylvania and remains subsisting so far as the records of this office show, as of the date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

SECRETARY OF THE COMMONWEALTH PENNSYLVANIA

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Veronica W. Degraffenreid

Acting Secretary of the Commonwealth

Certification Number: TSC210526131816-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

05/26/2021

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT,

Genoa Healthcare LLC

is duly registered as a Pennsylvania Limited Liability Company under the laws of the Commonwealth of Pennsylvania and remains subsisting so far as the records of this office show, as of the date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

SECRETARY OF THE COMMONWEALTH PENNSYLVANIA

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Veronica W. Degraffenreid

Acting Secretary of the Commonwealth

Certification Number: TSC210526131810-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

05/26/2021

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

Specialized Pharmaceuticals, Inc.

I, Veronica Degraffenreid, Acting Secretary of the Commonwealth of Pennsylvania, do hereby certify that the foregoing and annexed is a true and correct copy of

Creation Filing filed on May 26, 2000 - Pages (2)

which appear of record in this department.

SECRETARY OF THE COMMONWEALTH PENNSYLVANIA

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Veronica W. Degraffenreid

Acting Secretary of the Commonwealth

Certification Number: TSC210526131737-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

200042 - 338

DSCB 15 1306 (Rev 91)
P O NAEY COMPANY PGH PA 15219

Microfilm Number _____

Entity Number 2744023

Filed with the Department of State on MAY 26 2000

Kim Pizzingrilli
Secretary of the Commonwealth

ARTICLES OF INCORPORATION-FOR PROFIT
OF
SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation
A TYPE OF CORPORATION INDICATED BELOW

Indicate type of domestic corporation:

- ✓ Business stock (15 Pa C S § 1306)
- ___ Business nonstock (15 Pa C S § 2102)
- ___ Business statutory close (15 Pa C S § 2303)
- ___ Management (15 Pa C S § 2702)
- ___ Professional (15 Pa C S § 2903)
- ___ Insurance (15 Pa C S § 3101)
- ___ Cooperative (15 Pa C S § 7102)

DSCB 15 1306/2102/2303/2702/2903/3101/7102A (Rev 91)

In compliance with the requirements of the applicable provisions of 15 Pa C S (relating to corporations and unincorporated associations) the undersigned, desiring to incorporate a corporation for profit hereby, state(s) that:

1. The name of the corporation is Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's initial registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is

(a) 303 Perry Highway Pittsburgh, PA 15229 Allegheny
Number and Street City State Zip County

(b) c/o: _____ _____
Name of Commercial Registered Office Provider County

For a corporation represented by a commercial registered office provider, the county in (b) shall be deemed the county in which the corporation is located for venue and official publication purposes

3. The corporation is incorporated under the provisions of the Business Corporation Law of 1988

4. The aggregate number of shares authorized is 10,000 (other provisions, if any, attach 8 1/2 x 11 sheet)

5. The name and address, including number and street, if any, of each incorporator is:

Name	Address
Richard Bassano	600 Perry Highway Pgh, PA 15229

6. The specified effective date, if any, is: 6 - 1 - 00
month day year hour, if any

MAY 26 2000

200042 339

DSCB:15-1306/2102/2303/2702/2903/3101/7102A (Rev 91)-2

7. Additional provisions of the articles, if any, attach an 8 1/2 x 11 sheet.

8. **Statutory close corporation only**: Neither the corporation nor any shareholder shall make an offering of any of its shares of any class that would constitute a "public offering" within the meaning of the Securities Act of 1933 (15 U.S.C. § 77a et seq.)

9. **Cooperative corporations only**: (Complete and strike out inapplicable term) The common bond of membership among its members/shareholders is _____

IN TESTIMONY WHEREOF, the incorporator(s) has (have) signed these Articles of Incorporation this 24th day of May, 2000

(Signature)

(Signature)

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

05/26/2021

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

Genoa Healthcare LLC

I, Veronica Degraffenreid, Acting Secretary of the Commonwealth of Pennsylvania, do hereby certify that the foregoing and annexed is a true and correct copy of

Creation Filing filed on Jul 15, 2009 - Pages (2)

which appear of record in this department.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Veronica W. Degraffenreid

Acting Secretary of the Commonwealth

Certification Number: TSC210526090358-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

Entity #: 3893746
Date Filed: 07/15/2009
Pedro A. Cortés
Secretary of the Commonwealth

1965

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Entity Number

Certificate of Organization
Domestic Limited Liability Company
(15 Pa.C.S. § 8913)

Name
Address CT - COUNTER
City State Zip Code
76104-70 SQ PA

Document will be returned to the name and address you enter to the left.
⇐

Fee: $125

Commonwealth of Pennsylvania
CERTIFICATE OF ORGANIZATION 3 Page(s)

T0919647054

In compliance with the requirements of 15 Pa.C.S. § 8913 (relating to certificate of organization), the undersigned desiring to organize a limited liability company, hereby certifies that:

1. The name of the limited liability company *(designator is required, i.e., "company", "limited" or "limited liability company" or abbreviation)*:
QoL meds, LLC

2. The (a) address of the limited liability company's initial registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is:

(a) Number and Street	City	State	Zip	County
4900 Perry Highway, Building 2	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County

3. The name and address, including street and number, if any, of each organizer is *(all organizers must sign on page 2)*:

Name	Address
Lisa M. Jaras	401 Liberty Avenue, 22nd Floor, Three Gateway Center Pittsburgh, PA 15222-1005

2009 JUL 15 AM 7:15

{CLIENT WORK\34977\0000 H0566411.1}

DSCB:15-8913-2

4. *Strike out if inapplicable term*
~~A member's interest in the company is to be evidenced by a certificate of membership interest.~~

5. *Strike out if inapplicable:*
Management of the company is vested in a manager or managers.

6. The specified effective date, if any is: upon filing
month date year hour, if any

7. ~~*Strike out if inapplicable:* The company is a restricted professional company organized to render the following restricted professional service(s):~~

8. The term for which the Company is to exist is perpetual.

IN TESTIMONY WHEREOF, the organizer(s) has (have) signed this Certificate of Organization this

15th day of July, 2009.

Lisa M. Jaras

Lisa M. Jaras, Sole Organizer

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

05/04/2018

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

Specialized Pharmaceuticals, Inc.

I, Robert Torres, Acting Secretary of the Commonwealth of Pennsylvania, do hereby certify that the foregoing and annexed is a true and correct copy of

Creation Filing filed on May 26, 2000 - Pages (2)
Amendment filed on Oct 7, 2004 - Pages (2)
Merger filed on Apr 29, 2005 - Pages (6)
Amendment filed on Dec 5, 2006 - Pages (2)
Change of Address filed on Jul 19, 2007 - Pages (2)
Amendment filed on Nov 2, 2007 - Pages (3)
Amendment filed on Dec 3, 2007 - Pages (12)
Amendment filed on Mar 1, 2010 - Pages (3)
Survivor filed on Dec 5, 2013 - Pages (7)
Change of Address filed on Dec 4, 2014 - Pages (2)
Amendment filed on Jul 24, 2017 - Pages (1)

which appear of record in this department.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Robert Torres

Acting Secretary of the Commonwealth

Certification Number: TSC180504100430-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

200042 - 338

DSCB 15 1306 (Rev. 91)
P O MAILY COMPANY PHILA PA 19104

Microfilm Number _____ Filed with the Department of State on MAY 26 2000

Entity Number 2446023

Secretary of the Commonwealth

ARTICLES OF INCORPORATION-FOR PROFIT
OF
SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation
A TYPE OF CORPORATION INDICATED BELOW

Indicate type of domestic corporation:

✓ Business stock (15 Pa C.S. § 1306) ___ Management (15 Pa C.S. § 2702)

___ Business nonstock (15 Pa C.S. § 2102) ___ Professional (15 Pa C.S. § 2903)

___ Business statutory close (15 Pa C.S. § 2303) ___ Insurance (15 Pa C.S. § 3101)

___ Cooperative (15 Pa C.S. § 7102)

DSCB 15 1306/2102/2303/2702/2903/3101/7102A (Rev 91)

In compliance with the requirements of the applicable provisions of 15 Pa C.S. (relating to corporations and unincorporated associations) the undersigned, desiring to incorporate a corporation for profit hereby, state(s) that:

1. The name of the corporation is Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's initial registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is

(a) 203 Perry Highway Pittsburgh, PA 15229 Allegheny
Number and Street City State Zip County

(b) c/o: _____ _____
Name of Commercial Registered Office Provider County

For a corporation represented by a commercial registered office provider, the county in (b) shall be deemed the county in which the corporation is located for venue and official publication purposes.

3. The corporation is incorporated under the provisions of the Business Corporation Law of 1988.

4. The aggregate number of shares authorized is: 10,000 (other provisions, if any, attach 8 1/2 x 11 sheet)

5. The name and address, including number and street, if any, of each incorporator is:

Name Address

Richard Iessana 6000 Perry Highway Pgh, PA 15229

6. The specified effective date, if any, is: 6 - 1 - 00 _____
month day year hour, if any

MAY 26 2000

200042 339

DSCB:15-1306/2102/2303/2702/2903/3101/7102A (Rev 91)-2

7. Additional provisions of the articles, if any, attach an 8 1/2 x 11 sheet.

8. Statutory close corporation only: Neither the corporation nor any shareholder shall make an offering of any of its shares of any class that would constitute a 'public offering' within the meaning of the Securities Act of 1933 (15 U.S.C. § 77a et seq.).

9. Cooperative corporations only: (Complete and strike out inapplicable term) The common bond of membership among its members/shareholders is. _____

IN TESTIMONY WHEREOF, the incorporator(s) has (have) signed these Articles of Incorporation this 24th day of May, 2000

(Signature)

(Signature)

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Articles of Amendment-Domestic Corporation
(15 Pa.C.S.)

Entity Number
2944023

_X_ Business Corporation (§ 1915)
___ Nonprofit Corporation (§ 5915)

Name JENNIFER MARKS
Address PENNCORP SERVICEGROUP, INC.
600 NORTH SECOND STREET
City PO BOX 1210 State Zip Code
HARRISBURG PA 17108-1210

Document will be returned to the name and address you enter to the left. ⇐

Fee: $70

Filed in the Department of State on OCT 07 2004

Secretary of the Commonwealth

In compliance with the requirements of the applicable provisions (relating to articles of amendment), the undersigned, desiring to amend its articles, hereby states that:

1. The name of the corporation is:
Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
803 Perry Highway	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County
c/o

3. The statute by or under which it was incorporated: Pennsylvania Business Corporation Law of 1988

4. The date of its incorporation: May 26, 2000

5 *Check, and if appropriate complete, one of the following:*

_X_ The amendment shall be effective upon filing these Articles of Amendment in the Department of State.

___ The amendment shall be effective on: _____ Date _____ at _____ Hour

2004 OCT -7 PM 12:29

DSCB:15-1915 5915-2

200409 5- 137

6. *Check one of the following:*

_X_ The amendment was adopted by the shareholders or members pursuant to 15 Pa.C.S. § 1914(a) and (b) or § 5914(a).

____ The amendment was adopted by the board of directors pursuant to 15 Pa. C.S. § 1914(c) or § 5914(b).

7. *Check, and if appropriate, complete one of the following:*

_X_ The amendment adopted by the corporation, set forth in full, is as follows

"RESOLVED, that the proper officers of this corporation be and they hereby are authorized and directed to file the prescribed form of Articles of Amendment with the Office of the Secretary of the Commonwealth of Pennsylvania, amending Article Four (4) thereof to be and read as follows and that upon the filing of said Articles of Amendment it is hereby directed that such Articles of Amendment be inserted in the corporation's minute book as a part of the corporation's permanent records:

4. The aggregate number of shares authorized is 20,000."

8. *Check if the amendment restates the Articles:*

____ The restated Articles of Incorporation supersede the original articles and all amendments thereto.

IN TESTIMONY WHEREOF, the undersigned corporation has caused these Articles of Amendment to be signed by a duly authorized officer thereof this

__1st__ day of __October__, 2004

SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation

Signature

Richard Sassano, President
Title

200504.5-1367

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Articles/Certificate of Merger
(15 Pa.C.S.)

Entity Number
2944023

__X__ Domestic Business Corporation (§ 1926)
____ Domestic Nonprofit Corporation (§ 5926)
____ Limited Partnership (§ 8547)

Name: BELINDA SCHORY
Address: PENNCORP SERVICEGROUP, INC.
600 NORTH SECOND ST.
City: PO BOX 1210 State: PA Zip Code: 17108-1210

Document will be returned to the name and address you enter to the left. ⇐

Fee: $150 plus $40 additional for each Party in additional to two

Filed in the Department of State on APR 29 2005

Pedro A. Cortes

Secretary of the Commonwealth

In compliance with the requirements of the applicable provisions relating to articles of merger or consolidation, the undersigned, desiring to effect a merger, hereby state that:

1. The name of the corporation limited partnership surviving the merger is:
Specialized Pharmaceuticals, Inc.

2. *Check and complete one of the following:*

__X__ The surviving corporation limited partnership is a domestic business nonprofit corporation limited partnership and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
803 Perry Highway	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider: ____ County: ____
c/o

____ The surviving corporation limited partnership is a qualified foreign business nonprofit corporation limited partnership incorporated formed under the laws of ____ and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County

(b) Name of Commercial Registered Office Provider: ____ County: ____
c/o

____ The surviving corporation limited partnership is a nonqualified foreign business nonprofit corporation limited partnership incorporated formed under the laws of ____ and the address of its principal office under the laws of such jurisdiction is:

Number and Street	City	State	Zip

DSCB:15-1926 5926 8547-2

2005045-1368

3. The name and the address of the registered office in this Commonwealth or name of its commercial registered office provider and the county of venue of each other domestic business nonprofit corporation limited partnership and qualified foreign business nonprofit corporation limited partnership which is a party to the plan of merger are as follows:

Name	Registered Office Address	County
Qol Meds of Florida, Inc. -	Florida Business Corporation Not Qualified In Pennsylvania	

4. *Check and if appropriate complete one of the following*

_X_ The plan of merger shall be effective upon filing these Articles Certificate of Merger in the Department of State

____ The plan of merger shall be effective on _____ _____
Date Hour

5. The manner in which the plan of merger was adopted by each domestic corporation limited partnership is as follows:

Name	Manner of Adoption
Specialized Pharmaceuticals, Inc	Written Consent of Shareholders & Board of Directors pursuant to 15 Pa.C.S. § 1924(a)

6. *Strike out this paragraph if no foreign corporation limited partnership is a party to the merger*
The plan was authorized, adopted or approved, as the case may be, by the foreign business nonprofit corporation limited partnership (or each of the foreign business nonprofit corporations limited partnerships) party to the plan in accordance with the laws of the jurisdiction in which it is incorporated organized.

7. *Check and if appropriate complete one of the following*

_X_ The plan of merger is set forth in full in Exhibit A attached hereto and made a part hereof.

___ Pursuant to 15 Pa.C.S. § 1901 § 8547(b) relating to omission of certain provisions from filed plans) the provisions, if any, of the plan of merger that amend or constitute the operative provisions of the Articles of Incorporation/Certificate of Limited Partnership of the surviving corporation limited partnership as in effect subsequent to the effective date of the plan are set forth in full in Exhibit A attached hereto and made a party hereof. The full text of the plan of merger is on file at the principal place of business of the surviving corporation limited partnership, the address of which is:

Number and Street	City	State	Zip	County

MERGE (6/2001) (2)

2005045-1369

DSCB: 15-1926 5926 8547-3

IN TESTIMONY WHEREOF, the undersigned corporation limited partnership has caused these Articles Certificate of Merger to be signed by a duly authorized officer thereof this

28th day of April, 2005.

SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation Limited Partnership

Signature

Richard Sassano, President
Title

IN TESTIMONY WHEREOF, the undersigned corporation limited partnership has caused these Articles Certificate of Merger to be signed by a duly authorized officer thereof this

28th day of April, 2005

OCL MEDS OF FLORIDA, INC.
Name of Corporation Limited Partnership

Signature

Richard Sassano, President
Title

2005045-1370

EXHIBIT "A"
AGREEMENT AND PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER (this "Agreement") is made and entered into effective as of the 28th day of April, 2005, by and between SPECIALIZED PHARMACEUTICALS, INC., a Pennsylvania corporation (hereinafter referred to as "SPI") and QOL MEDS OF FLORIDA, INC., a Florida corporation (hereinafter referred to as "QoL").

WITNESSETH:

WHEREAS, SPI is a business corporation duly organized and validly existing under the laws of the Commonwealth of Pennsylvania, having been incorporated on May 26, 2000, and having authority to issue 20,000 shares of common stock, of which 11,125 shares are issued and outstanding; and

WHEREAS, QoL is a business corporation duly organized and validly existing under the laws of the State of Florida, having been incorporated on June 11, 2003, and having authority to issue 20,000 shares of common stock, of which 8,500 shares are issued and outstanding; and

WHEREAS, it is now the desire of SPI and QoL to merge their rights, privileges, franchises, permits and properties into one corporation in accordance with the terms and conditions hereinafter set forth, which corporation shall be hereinafter sometimes referred to as the "Surviving Corporation" and which corporation shall be the same corporation as SPI.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and intending to be legally bound hereby, the parties hereto agree as follows:

1. Effective Date. The merger provided for by this Agreement shall become effective upon the filing of the Articles of Merger with the Pennsylvania Department of State and Florida Department of State (hereinafter referred to as the "Effective Date").

2. Merger. Upon the Effective Date, QoL shall be merged into SPI, and the separate existence of QoL shall cease. SPI shall continue its corporate existence under the laws of the Commonwealth of Pennsylvania.

3. Articles of Incorporation. The Articles of Incorporation of the Surviving Corporation shall be the Articles of Incorporation of SPI.

4. Registered Office. The principal and registered office of the Surviving Corporation in the Commonwealth of Pennsylvania shall be 803 Perry Highway, Pittsburgh, Pennsylvania 15229.

5. Bylaws. The Bylaws of the Surviving Corporation shall be the Bylaws of SPI as they exist as of the date hereof.

2005045-1371

6. Directors and Officers. As of the Effective Date, the directors and officers of the Surviving Corporation shall be as follows:

Officers:		Directors:
President	Richard Sassano	Richard Sassano
Secretary/Treasurer	Richard Sassano	Robert Aul
		Michael Huffer

The directors and officers of the Surviving Corporation will continue to serve as such until their successors are duly elected and qualified.

Status of Shares of Stock.

On the Effective Date, by virtue of the Merger:

(a) All of the outstanding stock of QoL, including treasury stock, shall be canceled and the outstanding shares shall be exchanged for common stock of the Surviving Corporation ("Surviving Corporation Common Stock") as follows:

Richard Sassano - 3,000 shares
Daniel Sassano - 375 shares
Jeffrey Schneider - 375 shares
Keith Schneider - 375 shares

Such shares of Surviving Corporation Common Stock shall be delivered by Surviving Corporation to each respective shareholder of QoL on or after the Effective Date only upon surrender of the certificates representing the shares of QoL stock owned by such shareholder.

(b) Immediately upon the Merger's becoming effective, the equity interest of the shareholders of QoL as shareholders of QoL shall and be extinguished and their sole right shall be to receive the consideration as set forth above unless statutory dissenters rights have been preserved.

(c) Each outstanding share of Surviving Corporation Common Stock shall remain outstanding.

8. Effect of Merger. Upon this merger becoming effective:

(a) The Surviving Corporation shall possess all the rights, privileges, powers, licenses and franchises and shall be subject to all the restrictions, disabilities, obligations and duties of QoL;

(b) The Surviving Corporation shall be vested with all property, real, personal or mixed, and all debts due to QoL on whatever account, as well as all other choses in action relating to said corporation; and

200504 5-1372

(c) All property, rights, privileges, powers, licenses and franchises of QoL shall be the property of the Surviving Corporation; provided, however, that all rights of creditors and all liens upon any such property shall be preserved unimpaired, limited in lien to the property affected by such liens immediately prior to the Effective Date; and provided further, that all debts, obligations, liabilities and duties of QoL shall, as of the Effective Date, attached to and be assumed by the Surviving Corporation as if such debts, liabilities, obligations and duties had been incurred or contracted by it.

9. Shareholder Approval. Upon approval and execution of this Agreement and Plan of Merger by the Board of Directors and the shareholders of SPI and QoL, the Articles of Merger shall be duly executed on behalf of both corporations and said Articles shall be filed with the Department of State of the Commonwealth of Pennsylvania and the Department of State of the State of Florida.

10. Delivery of Documents. QoL agrees, as and when requested by the Surviving Corporation, to execute and deliver, or cause to be executed and delivered all documents, and to take or cause to be taken all actions as the Surviving Corporation may deem necessary or desirable in order to vest in the Surviving Corporation title to and possession of any property of QoL acquired or to be acquired by reason of this merger, and otherwise to carry out the intent and purposes hereof, and the proper officers and directors of QoL until the Effective Date, and the proper officers and directors of the Surviving Corporation after the Effective Date, are fully authorized in the name of QoL to take any and all such actions.

IN WITNESS WHEREOF, the parties have executed this Agreement and Plan of Merger as of the date and year first above written.

SPECIALIZED PHARMACEUTICALS, INC.

By: _____
Its: President

QoL MEDS OF FLORIDA, INC.

By: _____
Its: President

12-05-2006 02:27pm From-KRUSTON HARBAUGH 4122814491 T-

Entity #: 2944023
Date Filed: 12/05/2006
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Articles of Amendment-Domestic Corporation
(15 Pa.C.S.)

Entity Number
2944023

_X_ Business Corporation (§ 1915)
____ Nonprofit Corporation (§ 5915)

Name PENNCORP SERVICEGROUP, INC.
Address 600 NORTH SECOND STREET
PO BOX 1210
City HARRISBURG, PA 17108-1210 16788

Document will be returned to the name and address you enter to the left. ⇐

Fee: $70

Commonwealth of Pennsylvania
ARTICLES OF AMENDMENT-BUSINESS 2 Page(s)
10034060014

In compliance with the requirements of the applicable provisions (relating to articles of amendment), the undersigned, desiring to amend its articles, hereby states that:

1. The name of the corporation is:
Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
803 Perry Highway	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider
c/o

County

3. The statute by or under which it was incorporated: Pennsylvania Business Corporation Law of 1988

4. The date of its incorporation: May 26, 2000

5. *Check, and if appropriate complete, one of the following:*

_X_ The amendment shall be effective upon filing these Articles of Amendment in the Department of State.

____ The amendment shall be effective on: _____ at _____
Date Hour

IN 2006 DEC -5 PM 4:15

DSCB:15-1915/5915-2

6. *Check one of the following:*

_X_ The amendment was adopted by the shareholders or members pursuant to 15 Pa.C.S. § 1914(a) and (b) or § 5914(a).

____ The amendment was adopted by the board of directors pursuant to 15 Pa. C.S. § 1914(c) or § 5914(b).

7. *Check, and if appropriate, complete one of the following:*

_X_ The amendment adopted by the corporation, set forth in full, is as follows

"RESOLVED, that the proper officers of this corporation be and they hereby are authorized and directed to file the prescribed form of Articles of Amendment with the Office of the Secretary of the Commonwealth of Pennsylvania, amending Article 4 of the corporation's Articles of Incorporation to be and read as follows and that upon the filing of said Articles of Amendment with the Secretary of State, it is hereby directed that a date-stamped copy thereof be inserted in the corporation's minute book as a part of the corporation's permanent records:

'4. The aggregate number of shares authorized is 40,000.'"

8. *Check if the amendment restates the Articles:*

____ The restated Articles of Incorporation supersede the original articles and all amendments thereto.

IN TESTIMONY WHEREOF, the undersigned corporation has caused these Articles of Amendment to be signed by a duly authorized officer thereof this

24th day of October, 2006.

SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation

Signature

Richard Sexauer, President
Title

Entity #: 2944023
Date Filed: 07/19/2007
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Statement of Change of Registered Office (15 Pa.C.S.)

- [x] Domestic Business Corporation (§ 1507)
- [ ] Foreign Business Corporation (§ 4144)
- [ ] Domestic Nonprofit Corporation (§ 5507)
- [ ] Foreign Nonprofit Corporation (§ 6144)
- [ ] Domestic Limited Partnership (§ 8506)

Name
Richard Rizzo

Address
4900 Perry Highway Bldg 2 3rd Floor

City | State | Zip Code
Pittsburgh | PA | 15229

Document will be returned to the name and address you enter to the left. ⇐

Commonwealth of Pennsylvania
DOMESTIC - CHANGE OF REGISTERED OFFICE 2 Page(s)

T0720160067

Fee: $70

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. (relating to corporations and unincorporated associations), the undersigned corporation or limited partnership, desiring to effect a change of registered office, hereby states that:

1. The name is:
Specialized Pharmaceuticals, Inc

2. The (a) address of its initial registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is:

(a) Number and street | City | State | Zip | County
7440 McKnight Road | Pittsburgh | PA | 15237 | Allegheny

(b) Name of Commercial Registered Office Provider | County
c/o:

3. *Complete part (a) or (b):*

(a) The address to which the registered office of the corporation or limited partnership in this Commonwealth is to be changed is:

4900 Perry Highway Bldg 2 3rd Floor | Pittsburgh | PA | 15229 | Allegheny
Number and street | City | State | Zip | County

(b) The registered office of the corporation or limited partnership shall be provided by:

c/o:
Name of Commercial Registered Office Provider | County

PA DEPT. OF STATE

JUL 19 2007

DSCB:15-1507/4144/5507/6144/8506-2

4. *Strike out if a limited partnership:*

Such change was authorized by the Board of Directors of the corporation.

IN TESTIMONY WHEREOF, the undersigned has caused this Application for Registration to be signed by a duly authorized officer thereof this

13th day of July 2007

Specialized Pharmaceuticals, Inc

Name of Corporation/Limited Partnership

Signature

President/CEO

Title

11-02-2007 12:01pm From-HOUSTON HARBAUGH 4122814499 T-859

Entity #: 2944023
Date Filed: 11/02/2007
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Articles of Amendment-Domestic Corporation
(15 Pa.C.S.)

Entity Number
2944023

_X_ Business Corporation (§ 1915)
____ Nonprofit Corporation (§ 5915)

Name: BELINDA SCHORY
Address: PENNCORP SERVICE GROUP, INC
600 NORTH SECOND ST. # 2746
City: PO BOX 1210 Zip Code
HARRISBURG, PA 17108-1210

Document will be returned to the name and address you enter to the left.

Fee: $70

Commonwealth of Pennsylvania
ARTICLES OF AMENDMENT-BUSINESS 4 Page(s)

T0730647103

In compliance with the requirements of the applicable provisions (relating to articles of amendment), the undersigned, desiring to amend its articles, hereby states that:

1. The name of the corporation is:
Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
4900 Perry Highway, Building 2	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County
c/o

3. The statute by or under which it was incorporated: Pennsylvania Business Corporation Law of 1988

4. The date of its incorporation: May 26, 2000

5. Check, *and if appropriate complete, one of the following:*

_X_ The amendment shall be effective upon filing these Articles of Amendment in the Department of State.

____ The amendment shall be effective on: _____ at _____
Date Hour

PA DEPT. OF STATE
2007 NOV -2 PM 12:39

DSCB:15-1915/5915-2

6. *Check one of the following:*

__X__ The amendment was adopted by the shareholders or members pursuant to 15 Pa.C.S. § 1914(a) and (b) or § 5914(a).

_____ The amendment was adopted by the board of directors pursuant to 15 Pa. C.S. § 1914(c) or § 5914(b).

7. *Check, and if appropriate, complete one of the following:*

_____ The amendment adopted by the corporation, set forth in full, is as follows:

__X__ The amendment adopted by the corporation is set forth in full in Exhibit A attached hereto and made a part hereof.

8. *Check if the amendment restates the Articles:*

_____ The restated Articles of Incorporation supersede the original articles and all amendments thereto.

IN TESTIMONY WHEREOF, the undersigned corporation has caused these Articles of Amendment to be signed by a duly authorized officer thereof this

__31st__ day of __October__, __2007__.

SPECIALIZED PHARMACEUTICALS, INC.

Name of Corporation

Signature

President

Title

EXHIBIT "A"

TO ARTICLES OF AMENDMENT OF
ARTICLES OF INCORPORATION

OF

SPECIALIZED PHARMACEUTICALS, INC.

"RESOLVED, that Article 4 of the Articles of Incorporation of this corporation shall be amended to be and read as follows:

"4. The corporation shall have authority to issue twelve million (12,000,000) shares of stock, of which ten million (10,000,000) shares shall be common stock, at no par value per share, and two million (2,000,000) shares shall be preferred stock, at no par value per share. The Board of Directors may issue, in one or more classes or series, shares of preferred stock, with full, limited, multiple, fractional or no voting rights, and with such designations, preferences, qualifications, privileges, limitations, restrictions, options, conversion rights or other special or relative rights as shall be fixed from time to time by the Board of Directors.

Except as otherwise provided in any resolution or resolutions of the Board of Directors providing for the issuance of any particular class or series of preferred stock, the number of shares of stock of any such class or series as set forth in such resolution or resolutions may be increased or decreased (but not below the number of shares of such class or series then outstanding) by a resolution or resolutions adopted by the Board of Directors.

Except as otherwise provided in any resolution or resolutions of the Board of Directors providing for the issuance of any particular class or series of preferred stock, preferred stock redeemed or otherwise acquired by the corporation shall assume the status of authorized but unissued preferred stock, shall be unclassified as to class or series and may thereafter, subject to the provisions of this Article 4 and to any restrictions contained in any resolution or resolutions of the Board of Directors providing for the issue of any such class or series of preferred stock, be reissued in the same manner as other authorized but unissued preferred stock.'"

12-03-2007 11:40am From-HOUSTON HARBAUGH 4122814488 T-

Entity #: 2944023
Date Filed: 12/03/2007
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Entity Number
2944023

Statement with Respect to Shares
Domestic Business Corporation
(15 Pa.C.S. § 1522)

Name: BELINDA SCHORY
Address: ~~PENNCORP SERVICEGROUP, INC.~~ 600 NORTH SECOND ST. 2B422
City: ~~or~~ PO BOX 1210 Zip Code: ~~HARRISBURG PA~~ 17108-1210

Document will be returned to the name and address you enter to the left.
<=

Fee: $70

Commonwealth of Pennsylvania
STATEMENT WITH RESPECT TO SHARES 12 Page(s)

T07239847040

In compliance with the requirements of 15 Pa.C.S. § 1522(b) (relating to statement with respect to shares), the undersigned corporation, desiring to state the designation and voting rights, preferences, limitations, and special rights, if any, of a class or series of its shares, hereby states that:

1. The name of the corporation is:
Specialized Pharmaceuticals, Inc.

2. *Check and complete one of the following:*

____ The resolution amending the Articles under 15 Pa.C.S. § 1522(b) (relating to divisions and determinations by the board), set forth in full, is as follows:

_X_ The resolution amending the Articles under 15 Pa.C.S. § 1522(b) is set forth in full in Exhibit A attached hereto and made a part hereof.

3. The aggregate number of shares of such class or series established and designated by (a) such resolution, (b) all prior statements, if any, filed under 15 Pa.C.S. § 1522 or corresponding provisions of prior law with respect thereto, and (c) any other provision of the Articles is two million (2,000,000) shares of preferred stock, no par value per share, of which ninety thousand (90,000) shares are hereby designated as Series A Preferred Stock, to have the designation, rights, preferences, powers, restrictions and limitations as set forth in the attached resolution.

DOCUMENT NUMBER: 2007 DEC -3 P 12:40

DSCB:15-1522-2

4. The resolution was adopted by the Board of Directors or an authorized committee thereof on:
November 16, 2007

5. *Check, and if appropriate complete, one of the following:*

X The resolution shall be effective upon the filing of this statement with respect to shares in the Department of State.

____ The resolution shall be effective on: _____ at _____
Date Hour

IN TESTIMONY WHEREOF, the undersigned corporation has caused this statement to be signed by a duly authorized officer thereof this

27th day of November, 2007.

SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation

Signature

President
Title

EXHIBIT "A"
CERTIFICATE OF DESIGNATION OF SERIES A PREFERRED STOCK

(No Par Value)

OF

SPECIALIZED PHARMACEUTICALS, INC.

The undersigned duly authorized officer Specialized Pharmaceuticals, Inc., a corporation organized and existing under the laws of the Commonwealth of Pennsylvania (the "Company"), in accordance with the provisions of Section 1522 of the Business Corporation Law of 1988 of the Commonwealth of Pennsylvania, as amended, DOES HEREBY CERTIFY:

WHERREAS the Articles of Incorporation of the Company authorized preferred stock consisting of Two Million (2,000,000) shares, no par value, issuable from time to time in one or more series; and

WHERREAS, the Board of Directors of the Company is authorized, subject to limitations prescribed by law and by the provisions of Article 4 of the Company's Articles of Incorporation, as amended, to establish and fix the number of shares to be included in any series of preferred stock and the designation, rights, preferences, powers, restrictions and limitations of the shares of such series; and

WHERREAS, at a meeting of its members held on November 16, 2007, the Board of Directors established and fixed the number of shares to be included in a new series of preferred stock and the designation, rights, preferences and limitations of the shares of such new series as follows:

NOW, THEREFORE, BE IT RESOLVED that pursuant to Article 4 of the Company's Articles of Incorporation, as amended, there is hereby established a new series of Ninety Thousand (90,000) shares of preferred stock of the Company (the "Series A Preferred") to have the designation, rights, preferences, powers, restrictions and limitations as follows:

1. Dividends.

The holders of the Series A Preferred shall be entitled to receive, out of funds legally available therefore, non-cumulative dividends, when and as declared by the Board of Directors, in preference to any dividend on the common stock at a rate of eight percent (8%) per year of the Original Purchase Price as hereinafter defined.

2. Liquidation, Dissolution or Winding Up.

(a) In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A Preferred then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its shareholders, after and subject to the payment in full of all amounts required to be distributed to the holders of any other class or series of stock of the Company ranking on liquidation prior and in preference to the Series A Preferred (collectively referred to as "Senior Preferred Stock"), but before any payment shall be made to the holders of the common stock or any inferior preferred stock (the "Junior Stock") by reason of their ownership thereof, an amount equal to Sixty-Six and 67/100 Dollars ($66.67) (the "Original Purchase Price") per share of Series A Preferred plus any declared but unpaid dividends. If upon any such liquidation, dissolution or winding up of the Company the remaining assets of the Company available for distribution to its shareholders shall be insufficient to pay the holders of shares of Series

A Preferred the full amount to which they shall be entitled, the holders of shares of Series A Preferred and any class or series of stock (the "Preferred Stock") ranking on liquidation on a parity with the Series A Preferred shall share ratably in any distribution of the remaining assets and funds of the Company in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

(b) After the payment of all preferential amounts required to be upon the dissolution, liquidation, or winding up of the Company, all of the remaining assets and funds of the Company available for distribution to its shareholders shall be distributed ratably among the holders of the Series A Preferred, such other series of Preferred Stock as are constituted as similarly participating, and the common stock, with each share of Series A Preferred being deemed, for such purpose, to be equal to the number of shares of common stock, including fractions of a share, into which such share of Series A Preferred is convertible immediately prior to the close of business on the business day fixed for such distribution.

(c) A consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, or a sale, lease or other disposition of all or substantially all of the assets of the Company shall not be considered a liquidation under this Section.

3. Voting.

(a) General Rights. Except as otherwise required by law, each holder of Series A Preferred shall not be entitled to vote on any matter except as follows. The vote or written consent by the holders of at least fifty-one percent (51%) of the then outstanding shares of the Series A Preferred, voting separately as a class, shall be require to: (i) authorize or issue additional shares of Series A Preferred, (ii) authorize or issue any other equity security senior to or on a parity with the Series A Preferred as to liquidation preferences, conversion rights, voting rights, dividend rights or otherwise, (iii) sell, assign, lease or otherwise dispose of or voluntarily part with the control of (whether in one transaction or in a series of transactions) all, or substantially all, of the Company's assets (whether now owned or hereinafter acquired) or sell, assign or otherwise dispose of (whether in one transaction or in a series of transactions) any of the Companys's accounts receivable (whether now in existence or hereinafter created) at a discount or with recourse, to any person, or permit any subsidiary to do any of the foregoing, except for sales or other dispositions of assets in the ordinary course of business and except that (A) any subsidiary may merge into or consolidate with or transfer assets to any other subsidiary and (B) any subsidiary may merge into or transfer assets to the Company, (iv) take action that fundamentally alters the principal business of the Company as now conducted or as proposed to be conducted, or (v) authorize any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the shareholders of the Company immediately prior to such consolidation, merger or reorganization, own less than 50% of the Company's voting power immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions by the Company in which in excess of fifty percent (50%) of the Company's voting power is transferred.

(b) Election of Board of Directors. The holders of the Series A Preferred, voting together as a class, shall be entitled to elect one (1) member of the Company's Board of Directors. The holders of the common stock shall be entitled to elect all remaining members of the Board of Directors.

4. Optional Conversion.

The holders of the Series A Preferred shall have conversion rights as follows (the "Conversion Rights");

(a) Right to Convert. Each share of Series A Preferred shall be convertible, at the option of the holder thereof, at any time and from time to time, into such number of fully paid and nonassessable shares of common stock as is determined by dividing the Original Purchase Price by the Conversion Price (as defined below) in

effect at the time of conversion. The Conversion Price at which shares of common stock shall be deliverable upon conversion of Series A Preferred without the payment of additional consideration by the holder thereof (the "Conversion Price") shall initially be the Original Purchase Price per share. Such initial Conversion Price, and the rate at which shares of Series A Preferred may be converted into shares of common stock, shall be subject to adjustment as provided below.

In the event of a liquidation of the Company, the Conversion Rights shall terminate at the close of business on the first full day preceding the date fixed for the payment of any amounts distributable on liquidation to the holders of Series A Preferred.

(b) Fractional Shares. No fractional shares of common stock shall be issued upon conversion of the Series A Preferred. In lieu of fractional shares, the Company shall pay cash equal to such fraction multiplied by the then effective Conversion Price.

(c) Mechanics of Conversion.

(i) In order to convert shares of Series A Preferred into shares of common stock, the holder shall surrender the certificate or certificates for such shares of Series A Preferred at the office of the transfer agent (or at the principal office of the Company if the Company serves as its own transfer agent), together with written notice that such holder elects to convert all or any number of the shares represented by such certificate or certificates. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of common stock to be issued. If required by the Company, certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Company, duly executed by the registered holder or his or its attorney duly authorized in writing. The date of receipt of such certificates and notice by the transfer agent or the Company shall be the conversion date ("Conversion Date"). The Company shall, as soon as practicable after the Conversion Date, issue and deliver at such office to such holder, or to his nominees, a certificate or certificates for the number of shares of common stock to which such holder shall be entitled, together with cash in lieu of any fraction of a share.

(ii) The Company shall at all times during which the Series A Preferred shall be outstanding, reserve and keep available out of its authorized but unissued stock, for the purpose of effecting the conversion of the Series A Preferred, such number of its duly authorized shares of common stock as shall from time to time be sufficient to effect the conversion of all outstanding Series A Preferred.

(iii) Upon any such conversion, no adjustment to the Conversion Price shall be made for any declared and unpaid dividends on the Series A Preferred surrendered for conversion or on the common stock delivered upon conversion; the holder, by converting, waives his right to such declared but unpaid dividends.

(iv) All shares of Series A Preferred, which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares, including the rights, if any, to receive dividends, notices and to vote, shall immediately cease and terminate on the Conversion Date, except only the right of the holders thereof to receive shares of common stock in exchange therefor. Any shares of Series A Preferred so converted shall be retired and cancelled and shall not be reissued, and the Company may from time to time take such appropriate action as may be necessary to reduce the number of shares of authorized Series A Preferred accordingly.

(d) Adjustments to Conversion Price for Dilutive Issues.

(i) Special Definitions. For purposes of this Subsection 4(d), the following definitions shall apply:

(A) "Option" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire common stock or Convertible Securities, excluding rights or options granted to employees, directors or consultants of the Company pursuant to an option plan adopted by the Board of Directors to acquire up to that number of shares of common stock as is equal to ten (10%) percent of the common stock outstanding (provided that, for purposes of this Subsection 4(d)(i)(A), all shares of common stock issuable upon (1) exercise of options granted or available for grant under plans approved by the Board of Directors, (2) conversion of shares of Preferred Stock, or (3) conversion of Preferred Stock issuable upon conversion or exchange of any Convertible Security, shall be deemed to be outstanding), minus the total number of Key Employee Shares (as defined below).

(B) "Original Issue Date" shall mean the date on which the first share of Series A Preferred is first issued.

(C) "Convertible Securities" shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for common stock.

(D) "Additional Shares of common stock" shall mean all shares of common stock issued (or, pursuant to Subsection 4(d)(iii) below, deemed to be issued) by the Company after the Original Issue Date, other than Key Employee Shares (as defined below) and other than shares of common stock issued or issuable:

(1.) as a dividend or distribution on Series A Preferred;

(2.) by reason of a dividend, stock split, split up or other distribution on shares of common stock excluded from the definition of Additional Shares of common stock by the foregoing clause (1);

(3.) upon the exercise of options excluded from the definition of "Option" in Subsection 4(d)(i)(A); or

(4.) upon conversion of shares of Series A Preferred;

(5.) upon conversion of Convertible Securities existing as of the date of this Certificate; or

(6.) upon conversion of the Convertible Line of Credit Note with Daniel Sassano in the amount of $600,000.

(E) "Key Employee Shares" shall mean shares of common stock issued to directors or key employees of or consultants to the Company pursuant to a restricted stock plan or agreement approved by the Board of Directors, up to that number of shares of common stock as is equal to ten (10%) percent of the common stock outstanding (provided that, for purposes of this Subsection 4(d)(i)(E), all shares of common stock issuable upon (1) exercise of options granted or available for grant under plans approved by the Board of Directors, (2) conversion of shares of Preferred Stock, or (3) upon conversion of Preferred Stock issuable upon conversion or exchange of any Convertible Security, shall be deemed to be outstanding), minus the total number of shares subject to or issued pursuant to options excluded from the definition of "Option" in paragraph (A)

above (subject to appropriate adjustment for any stock dividend, stock split, combination or similar recapitalization affecting such shares).

(F) "Rights to Acquire common stock" (or "Rights") shall mean all rights issued by the Company to acquire common stock whatever by exercise of a warrant, option or similar call or conversion of any existing instruments, in either case for consideration fixed, in amount or by formula, as of the date of issuance.

(ii) No Adjustment of Conversion Price. No adjustment in the number of shares of common stock into which the Series A Preferred is convertible shall be made, by adjustment in the applicable Conversion Price thereof: (a) unless the consideration per share (determined pursuant to Subsection 4(d)(v)) below for an Additional Share of common stock issued or deemed to be issued by the Company is less than the applicable Conversion Price in effect on the date of, and immediately prior to, the issue of such additional shares, or (b) if prior to such issuance, the Company receives written notice from the holders of at least fifty one percent (51%) of the then outstanding shares of Series A Preferred agreeing that no such adjustment shall be made as the result of the issuance of Additional Shares of common stock.

(iii) Issue of Securities Deemed Issue of Additional Shares of common stock. If the Company at any time or from time to time after the Original Issue Date shall issue any Options or Convertible Securities or other Rights to Acquire common stock, then the maximum number of shares of common stock (as set forth in the instrument relating thereto without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options, Rights or, in the case of Convertible Securities, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of common stock issued as of the time of such issue, provided that Additional Shares of common stock shall not be deemed to have been issued unless the consideration per share (determined pursuant to Subsection 4(d)(v) hereof) of such Additional Shares of common stock would be less than the applicable Conversion Price in effect on the date of and immediately prior to such issue, or such record date, as the case may be, and provided further that in any such case in which Additional Shares of common stock are deemed to be issued:

(A) No further adjustment in the Conversion Price shall be made upon the subsequent issue of shares of common stock upon the exercise of such Rights or conversion or exchange of such Convertible Securities;

(B) Upon the expiration or termination of any unexercised Option or Right, the Conversion Price shall not be readjusted, but the Additional Shares of common stock deemed issued as the result of the original issue of such Option or Right shall not be deemed issued for the purposes of any subsequent adjustment of the Conversion Price; and

(C) In the event of any change in the number of shares of common stock issuable upon the exercise, conversion or exchange of any Option, Right or Convertible Security, including, but not limited to, a change resulting from the anti dilution provisions thereof, the Conversion Price then in effect shall forthwith be readjusted to such Conversion Price as would have obtained had the adjustment that was made upon the issuance of such Option, Right or Convertible Security not exercised or converted prior to such change been made upon the basis of such change, but no further adjustment shall be made for the actual issuance of common stock upon the exercise or conversion of any such Option, Right or Convertible Security.

(iv) Adjustment of Conversion Price upon Issuance of Additional Shares of common stock. If the Company shall at any time after the Original Issue Date issue Additional Shares of common stock (including Additional Shares of common stock deemed to be issued pursuant to Subsection 4(d)(iii), but excluding shares issued as a dividend or distribution as provided in Subsection 4(f) or upon a stock split or combination as provided in Subsection 4(e)), without consideration or for a consideration per share less than the

applicable Conversion Price in effect on the date of and immediately prior to such issue, then and in such event, such Conversion Price shall be reduced, concurrently with such issue to a price (calculated to the nearest cent) determined by multiplying such Conversion Price by a fraction, (a) the numerator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issue plus (2) the number of shares of common stock which the aggregate consideration received by the Company for the total number of Additional Shares of common stock so issued would purchase at such Conversion Price; and (b) the denominator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issue plus (2) the number of such Additional Shares of common stock so issued.

Notwithstanding the foregoing, the applicable Conversion Price shall not be reduced if the amount of such reduction would be an amount less than $.05, but any such amount shall be carried forward and reduction with respect thereto made at the time of and together with any subsequent reduction which, together with such amount and any other amount or amounts so carried forward, shall aggregate $.05 or more.

(v) Determination of Consideration. For purposes of this Subsection 4(d), the consideration received by the Company for the issue of any Additional Shares of common stock shall be computed as follows:

(A) Cash and Property: Such consideration shall:

(1.) insofar as it consists of cash, be computed at the aggregate of cash received by the Company, excluding amounts paid or payable for accrued interest or accrued dividends;

(2.) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors; and

(3.) in the event Additional Shares of common stock are issued together with other shares or securities or other assets of the Company for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (1) and (2) above, as determined in good faith by the Board of Directors.

(B) Options, Rights and Convertible Securities. The consideration per share received by the Company for Additional Shares of common stock deemed to have been issued pursuant to Subsection 4(d)(ii), relating to Options, Rights and Convertible Securities, shall be determined by dividing

(1.) the total amount, if any, received or receivable by the Company as consideration for the issue of such Options, Rights or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Company upon the exercise of such Options, Rights or the conversion or exchange of such Convertible Securities, by

(2.) the maximum number of shares of common stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities.

(e) Adjustment for Stock Splits and Combinations. If the Company shall at any time or from time to time after the Original Issue Date effect a subdivision of the outstanding common stock, the Conversion Price then in effect immediately before that subdivision shall be proportionately decreased. If the Company shall at any time or from time to time after the Original Issue Date combine the outstanding shares of common stock, the Conversion Price then in effect immediately before the combination shall be proportionately increased. Any

adjustment under this paragraph shall become effective at the close of business on the date the subdivision or combination becomes effective.

(f) Adjustment for Certain Dividends and Distributions. In the event the Company at any time, or from time to time after the Original Issue Date shall make or issue, a dividend or other distribution payable in Additional Shares of common stock, then and in each such event the Conversion Price shall be decreased as of the time of such issuance, by multiplying the Conversion Price by a fraction:

(i) the numerator of which shall be the total number of shares of common stock issued and outstanding immediately prior to the time of such issuance, and

(ii) the denominator of which shall be the total number of shares of common stock issued and outstanding immediately prior to the time of such issuance plus the number of shares of common stock issuable in payment of such dividend or distribution.

(g) Adjustments for Other Dividends and Distributions. In the event the Company at any time or from time to time after the Original Issue Date shall make or issue a dividend or other distribution payable in securities of the Company other than shares of common stock, then and in each such event provision shall be made so that the holders of shares of the Series A Preferred shall receive upon conversion thereof in addition to the number of shares of common stock receivable thereupon, the amount of securities of the Company that they would have received had their Series A Preferred been converted into common stock on the date of such event and had thereafter, during the period from the date of such event to and including the conversion date, retained such securities receivable by them as aforesaid during such period given application to all adjustments called for during such period, under this paragraph with respect to the rights of the holders of the Series A Preferred.

(h) Adjustment for Reclassification, Exchange, or Substitution. If the common stock issuable upon the conversion of the Series A Preferred shall be changed into the same or a different number of shares of any class or classes of stock, whether by capital reorganization, reclassification, or otherwise (other than a subdivision or combination of shares or stock dividend provided for above, or a reorganization, merger, consolidation, or sale of assets for below), then and in each such event the holder of each share of Series A Preferred shall have the right thereafter to convert such share into the kind and amount of shares of stock and other securities and property receivable upon such reorganization, reclassification, or other change, by holders of the number of shares of common stock into which such shares of Series A Preferred might have been converted immediately prior to such reorganization, reclassification, or change, all subject to further adjustment as provided herein.

(i) Adjustment for Merger or Reorganization, etc. In case of any consolidation or merger of the Company with or into another corporation or the sale of all or substantially all of the assets of the Company to another corporation,

(i) if the surviving entity shall consent in writing to the following provisions, then each share of Series A Preferred shall thereafter be convertible into the kind and amount of shares of stock or other securities or property to which a holder of the number of shares of common stock of the Company deliverable upon conversion of such Series A Preferred would have been entitled upon such consolidation, merger or sale; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions in this Section 4 set forth with respect to the rights and interest thereafter of the holders of the Series A Preferred, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any shares of stock or other property thereafter deliverable upon the conversion of the Series A Preferred; or

(ii) if the surviving entity shall not so consent, then each holder of Series A Preferred may, after receipt of notice specified in subsection (i), elect to convert such Stock into Common Shares as provided in this Section 4 or to accept the distributions to which he shall be entitled under Section 2(a) through (c).

(j) No Impairment. The Company will not, by amendment of its Articles of Incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Section 4 and in the taking of all such action as may be necessary or appropriate in order to protect the Conversion Rights of the holders of the Series A Preferred against impairment.

(k) Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the Conversion Price pursuant to this Section 4, the Company at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder, if any, of Series A Preferred a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based and shall file a copy of such certificate with its corporate records. The Company shall, upon the written request at any time of any holder of Series A Preferred, furnish or cause to be furnished to such holder a similar certificate setting forth (1) such adjustments and readjustments, (2) the Conversion Price then in effect, and (3) the number of shares of common stock and the amount, if any, of other property which then would be received upon the conversion of Series A Preferred. Despite such adjustment or readjustment, the form of each or all Series A Preferred Certificates, if the same shall reflect the initial or any subsequent conversion price, need not be changed in order for the adjustments or readjustments to be valued in accordance with the provisions of this Certificate of Designation, which shall control.

(l) Notice of Record Date. In the event:

(i) that the Company declares a dividend (or any other distribution) on its common stock payable in common stock or other securities of the Company;

(ii) that the Company subdivides or combines its outstanding shares of common stock;

(iii) of any reclassification of the common stock of the Company (other than a subdivision or combination of its outstanding shares of common stock or a stock dividend or stock distribution thereon), or of any consolidation or merger of the Company into or with another corporation, or of the sale of all or substantially all of the assets of the Company; or

(iv) of the involuntary or voluntary dissolution, liquidation or winding up of the Company;

then the Company shall cause to be filed at its principal office or at the office of the transfer agent of the Series A Preferred, and shall cause to be mailed to the holders of the Series A Preferred at their last addresses as shown on the records of the Company or such transfer agent, at least ten days prior to the record date specified in (A) below or twenty days before the date specified in (B) below, a notice stating

(A) the record date of such dividend, distribution, subdivision or combination, or, if a record is not to be taken, the date as of which the holders of common stock of record to be entitled to such dividend, distribution, subdivision or combination are to be determined, or

(B) the date on which such reclassification, consolidation, merger, sale, dissolution, liquidation or winding up is expected to become effective, and the date as of which it is expected that holders of common stock of record shall be entitled to exchange their shares of common stock for securities or other property deliverable upon such reclassification, consolidation, merger, sale, dissolution or winding up.

5. Mandatory Conversion.

(a) The holders of shares of Series A Preferred then outstanding shall be required to convert all their shares of Series A Preferred into shares of common stock, at the then effective conversion rate pursuant to Section 4, (1) immediately prior to the closing of the sale of shares of common stock, at a price per share which exceeds 300% of the Conversion Price then in effect, in a fully, underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, other than a registration relating solely to a transaction under Rule 145 under such Act (or any successor thereto) or to an employee benefit plan of the Company, underwritten by a reputable underwriter acceptable to the holders of a majority of the then outstanding Series A Preferred, resulting in at least $10,000,000 of gross proceeds to the Company, or (2), upon the vote of Sixty-Six and 67/100 percent (66.67%) of the outstanding shares of Series A Preferred.

(b) All holders of record of shares of Series A Preferred then outstanding will be given at least ten (10) days prior written notice of the date fixed and the place designated for mandatory conversion of all such shares of Series A Preferred pursuant to this Section 5. Such notice will be sent by first class or registered mail, postage prepaid, to each record holder of Series A Preferred at such holder's address last shown on the records of the transfer agent for the Series A Preferred (or the records of the Company, if it serves as its own transfer agent).

6. Redemption of the Series A Preferred.

(a) Commencing not earlier than October 30, 2012, the Company shall, at the written request of holders of a majority of the outstanding shares of Series A Preferred, redeem all of the Series A Preferred. The redemption price for each share of Series A Preferred shall be the Original Purchase Price per share plus all declared and unpaid dividends. The redemption shall occur within One Hundred and Twenty (120) days of the request from holders of the Series A Preferred.

(b) Commencing not earlier than October 30, 2012, the Company shall have the option by delivery of notice to all the holders of the outstanding shares of Series A Preferred, to redeem all of the Series A Preferred. The Notice shall be provided to all the holders of the outstanding shares of Series A Preferred not less than sixty (60) days prior to the date of redemption. The redemption price for each share of Series A Preferred shall be One Hundred and Twenty ($120.00) per share plus all declared and unpaid dividends.

(c) The notice by the Company of the exercise of the redemption option pursuant to Section 6(a) or (b) of this Section 6 shall be sent by first class certified mail, postage prepaid and return receipt requested to all holders of the shares of Series A Preferred at their respective addresses as the same shall appear on the books of the Company.

(d) If upon the Redemption Date the assets of the Company available for redemption are insufficient to pay the holders of outstanding shares of Series A Preferred the full amounts to which they are entitled, such holders of shares of Series A Preferred shall share ratably according to the respective amounts which would be payable in respect of such shares to be redeemed by the holders thereof, if all amounts payable on or with respect to such shares were paid in full.

(e) Any shares of Series A Preferred redeemed pursuant to this Section or otherwise acquired by the Company in any manner whatsoever shall be canceled and shall not under any circumstances be reissued; the Company may from time to time take such appropriate corporate action as may be necessary to reduce accordingly the number of authorized shares of the Company's capital stock.

(f) Anything contained in this Section 6 to the contrary notwithstanding, the holders of shares of Series A Preferred to be redeemed in accordance with this Section shall have the right, exercisable at any time up to the close of business on the applicable redemption date (unless the Company is legally prohibited from redeeming such shares on such date, in which event such right shall be exercisable until the removal of such legal disability), to convert all or any part of such shares to be redeemed as herein provided into shares of common stock pursuant to Section 4 hereof.

7. Amendment.

This Certificate of Designation constitutes an agreement between the Company and the holders of the Series A Preferred. It may be amended by vote of the Board of Directors of the Company and the holders of a majority of the outstanding shares of Series A Preferred.

MAR-01-2010 10:57 From:HOUSTON HARBAUGH 412 281 4499 To:SOS8305

Entity#: 2944023
Date Filed: 03/01/2010
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Articles of Amendment-Domestic Corporation
(15 Pa.C.S.)

Entity Number
2944023

_X_ Business Corporation (§ 1915)
____ Nonprofit Corporation (§ 5915)

Name
PENNCORP SERVICEGROUP, INC.
600 NORTH SECOND STREET
PO BOX 1210
HARRISBURG, PA 17108-1210

1597

Document will be returned to the name and address you enter to the left.

Fee: $70

Commonwealth of Pennsylvania
ARTICLES OF AMENDMENT-BUSINESS 4 Page(s)

T1006147049

In compliance with the requirements of the applicable provisions (relating to articles of amendment), the undersigned, desiring to amend its articles, hereby states that:

1. The name of the corporation is:
Specialized Pharmaceuticals, Inc.

2. The (a) address of this corporation's current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
4900 Perry Highway, Building 2	Pittsburgh	Pennsylvania	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County

c/o

3. The statute by or under which it was incorporated: Pennsylvania Business Corporation Law of 1988

4. The date of its incorporation: May 26, 2000

5. *Check, and if appropriate complete, one of the following:*

_X_ The amendment shall be effective upon filing these Articles of Amendment in the Department of State.

____ The amendment shall be effective on: _____ at _____
Date Hour

2010 MAR -1 PM 12:43

PA STATE

DSCB:15-1915/5915-2

6. *Check one of the following:*

___ The amendment was adopted by the shareholders or members pursuant to 15 Pa.C.S. § 1914(a) and (b) or § 5914(a).

_X_ The amendment was adopted by the board of directors pursuant to 15 Pa. C.S. § 1914(c) or § 5914(b).

7. *Check, and if appropriate, complete one of the following:*

___ The amendment adopted by the corporation, set forth in full, is as follows

_X_ The amendment adopted by the corporation is set forth in full in Exhibit A attached hereto and made a part hereof.

8. *Check if the amendment restates the Articles:*

___ The restated Articles of Incorporation supersede the original articles and all amendments thereto.

IN TESTIMONY WHEREOF, the undersigned corporation has caused these Articles of Amendment to be signed by a duly authorized officer thereof this

25th day of, February, 2010.

SPECIALIZED PHARMACEUTICALS, INC.
Name of Corporation

Signature

James Smith, President
Title

EXHIBIT "A"

TO ARTICLES OF AMENDMENT OF
ARTICLES OF INCORPORATION

OF

SPECIALIZED PHARMACEUTICALS, INC.

RESOLVED, that for the purpose of facilitating doing business in other states and reducing the amount of franchise tax paid to those states, the Board of Directors hereby proposes that the Corporation's Articles of Incorporation be so amended as to designate a par value of one cent ($.01) to each share of the Corporation's authorized capital stock; and be it further

"RESOLVED, that in order to effect this change in the par value of the Corporation's stock, the proper officers of this Corporation be and they hereby are authorized and directed to file the prescribed form of Articles of Amendment with the Secretary of the Commonwealth of Pennsylvania so as to amend the first paragraph of Article 4 thereof so that, as amended, said paragraph shall be and read as follows:

'4. The corporation shall have authority to issue twelve million (12,000,000) shares of stock of which ten million (10,000,000) shares shall be common stock, at one cent ($.01) par value per share, and two million (2,000,000) shares shall be preferred stock, at one cent ($.01) par value per share. The Board of Directors may issue, in one or more classes or series, shares of preferred stock, with full, limited, multiple, fractional or no voting rights, and with such designations, preferences, qualifications, privileges, limitations, restrictions, options, conversion rights or other special or relative rights as shall be fixed from time to time by the Board of Directors.'

RESOLVED, that upon the filing of the Articles of Amendment with the Secretary of the Commonwealth of Pennsylvania, the Secretary of the Corporation is hereby authorized and directed to insert a date-stamped copy thereof in the minute book of the Corporation as a part of the Corporation's permanent records."

Entity #: 2844023
Date Filed: 12/05/2013
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Articles/Certificate of Merger

(15 Pa.C.S.)

__X__ Domestic Business Corporation (§ 1926)
____ Domestic Nonprofit Corporation (§ 5926)
____ Limited Partnership (§ 8547)

Name

910469-005 Ken
Corporation Service Company

Commonwealth of Pennsylvania
ARTICLES OF MERGER-BUSINESS 6 Page(s)

71334011809

Fee: $150 plus $40 additional for each
Party in additional to two

In compliance with the requirements of the applicable provisions (relating to articles of merger or consolidation), the undersigned, desiring to effect a merger, hereby state that:

1. The name of the corporation/limited partnership surviving the merger is:
Specialized Pharmaceuticals, Inc.

2. *Check and complete one of the following:*

__X__ The surviving corporation/limited partnership is a domestic business/nonprofit corporation/limited partnership and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
4900 Perry Hwy., Bldg. 2, 3rd Floor	Pittsburgh	PA	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County
c/o

____ The surviving corporation/limited partnership is a qualified foreign business/nonprofit corporation/limited partnership incorporated/formed under the laws of _____ and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street — City — State — Zip — County

(b) Name of Commercial Registered Office Provider — County
c/o

____ The surviving corporation/limited partnership is a nonqualified foreign business/nonprofit corporation/limited partnership incorporated/formed under the laws of _____ and the address of its principal office under the laws of such domiciliary jurisdiction is:

Number and Street — City — State — Zip

2013 DEC -5 PM 4:38
PA DEPT OF STATE

DSCB:15-1926/3926/8547–2

3. The name and the address of the registered office in this Commonwealth or name of its commercial registered office provider and the county of venue of each other domestic business/nonprofit corporation/limited partnership and qualified foreign business/nonprofit corporation/limited partnership which is a party to the plan of merger are as follows:

Name	Registered Office Address	Commercial Registered Office Provider	County
SPI Merger Sub, Inc. (DE not qualified in PA)			

4. *Check, and if appropriate complete, one of the following:*

X The plan of merger shall be effective upon filing these Articles/Certificate of Merger in the Department of State.

___ The plan of merger shall be effective on: ___ ___ ___ at ___.
Date Hour

5. The manner in which the plan of merger was adopted by each domestic corporation/limited partnership is as follows:

Name	Manner of Adoption
Specialized Pharmaceuticals, Inc.	Adopted by the directors and shareholders pursuant to 15 Pa.C.S. § 1924(a)

6. *Strike out this paragraph if no foreign corporation/limited partnership is a party to the merger.* The plan was authorized, adopted or approved, as the case may be, by the foreign business/nonprofit corporation/limited partnership (or each of the foreign business/nonprofit corporations/limited partnerships) party to the plan in accordance with the laws of the jurisdiction in which it is incorporated/organized.

7. *Check, and if appropriate complete, one of the following:*

___ The plan of merger is set forth in full in Exhibit A attached hereto and made a part hereof.

X Pursuant to 15 Pa.C.S. § 1901/§ 8547(b) (relating to omission of certain provisions from filed plans) the provisions, if any, of the plan of merger that amend or constitute the operative provisions of the Articles of Incorporation/Certificate of Limited Partnership of the surviving corporation/limited partnership as in effect subsequent to the effective date of the plan are set forth in full in Exhibit A attached hereto and made a party hereof. The full text of the plan of merger is on file at the principal place of business of the surviving corporation/limited partnership, the address of which is:

c/o Vivo Meds, LLC, 4900 Perry Hwy, Bldg. 2, 3rd Floor, Pittsburgh, PA 15229

Number and Street	City	State	Zip	County

DSCB: 15-1926/5926/8547-3

IN TESTIMONY WHEREOF, the undersigned corporation/limited partnership has caused these Articles/Certificate of Merger to be signed by a duly authorized officer thereof this

5th day of December,

2018.

SPECIALIZED PHARMACEUTICALS, INC.

Name of Corporation/Limited Partnership

Signature

Chief Executive Officer

Title

SPI MERGER SUB, INC.

Name of Corporation/Limited Partnership

Signature

President

Title

DSCB: 15-1926/5926/8547-3

IN TESTIMONY WHEREOF, the undersigned corporation/limited partnership has caused these Articles/Certificate of Merger to be signed by a duly authorized officer thereof this

5th day of December

2013

SPECIALIZED PHARMACEUTICALS, INC.

Name of Corporation/Limited Partnership

Signature

Chief Executive Officer

Title

SPI MERGER SUB, INC.

Name of Corporation/Limited Partnership

Signature

President

Title

AMENDED AND RESTATED ARTICLES OF INCORPORATION

OF

SPECIALIZED PHARMACEUTICALS, INC.

Specialized Pharmaceuticals, Inc., a corporation organized and existing under the laws of the Commonwealth of Pennsylvania (the "Corporation"), hereby amends and restates, under the provisions and subject to the requirements of the Pennsylvania Business Corporation Law of 1988, as amended (the "PaBCL") and hereby certifies as follows:

1. The name of the Corporation is Specialized Pharmaceuticals, Inc.

2. The Corporation filed, with the Secretary of the Commonwealth of Pennsylvania, its original Articles of Incorporation on May 26, 2000 (as amended from time to time, the "Current Articles of Incorporation").

3. The text of the Current Articles of Incorporation is hereby amended and restated in its entirety to provide as follows:

FIRST: The name of the corporation (hereinafter called the "Corporation") is Specialized Pharmaceuticals, Inc.

SECOND: The name of the Corporation's Commercial Registered Office Provider is c/o Corporation Service Company and the county of venue is Dauphin.

THIRD: The nature of the business or purposes to be conducted by and promoted by the Corporation is to engage in any lawful act or activity for which corporations may be organized under the PaBCL.

FOURTH: The total number of shares of stock which the Corporation shall have authority to issue is three thousand (3,000) shares of Common Stock with a par value of $.01 per share.

FIFTH: To the fullest extent permitted by the PaBCL, a Director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a Director; provided, however, that the foregoing clause shall not apply to any liability of a Director for acts or omissions taken in bad faith or which involve fraud or intentional misconduct. This Article shall not eliminate or limit the liability of a Director for any act or omission occurring prior to the time this Article became effective.

SIXTH: The Corporation is to have perpetual existence.

SEVENTH: Elections of Directors need not be by written ballot unless the By-laws of the Corporation so provide.

EIGHTH: In furtherance and not in limitation of the powers conferred by the laws of Pennsylvania, the Board of Directors of the Corporation is authorized and empowered to adopt, alter, amend and repeal the By-laws of the Corporation in any manner not inconsistent with the laws of Pennsylvania.

NINTH: The Corporation shall indemnify its officers, directors, employees and agents to the extent set forth in the By-laws of the Corporation. Such indemnification shall not be exclusive of other indemnification rights arising under any by-law, agreement, vote of directors or stockholders or otherwise and shall inure to the benefit of the heirs and legal representatives of such person.

TENTH: Meetings of the stockholders may be held within or without the Commonwealth of Pennsylvania, as the By-laws may provide. The books of the Corporation may be kept (subject to any provision contained in the statutes) outside the Commonwealth of Pennsylvania at such place or places as may be designated from time to time by the Board of Directors or in the By-laws of the Corporation.

ELEVENTH: The Corporation reserves the right to amend, alter, change or repeal any provision contained in these Articles of Incorporation, in the manner now or hereafter prescribed by statute.

IN WITNESS WHEREOF, this Amended and Restated Articles of Incorporation has been executed by a duly authorized officer of this Corporation on this 11th day of December, 2013.

Name: James Smith
Title: President / CEO

Entity #: 2844828
Date Filed: 12/04/2014
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement or Certificate of Change of Registered Office (15 Pa.C.S.) for

(check one):

- ___ Domestic Business Corporation (§ 1507)
- X Foreign Business Corporation (§ 4144)
- ___ Domestic Nonprofit Corporation (§ 5507)
- ___ Foreign Nonprofit Corporation (§ 5144)
- ___ Domestic Limited Partnership (§ 8506)
- ___ Domestic Limited Liability Company (§ 8906)

Name: CT - COUNTER

Address:

City: 9364128 State: SOPA Zip Code: 10

Document will be returned to the name and Commonwealth of Pennsylvania FOREIGN BUSINESS CHARGE OF REGISTERED OFFICE 2 Page(s)

T1484341057

Fee: $5

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. (relating to change of registered office), the undersigned corporation, limited partnership or limited liability company, desiring to effect a change of registered office, hereby states that:

1. The name is:
SPECIALIZED PHARMACEUTICALS, INC.

2. Current address as registered with the Department of State. *Complete part (a) or (b) – not both:*

(a) The address of its current registered office in this Commonwealth is:

4900 Perry Hwy Bldg 2 3rd Fl	Pittsburgh	PA	15229	Allegheny
Number and street	City	State	Zip	County

(b) The name of its current commercial registered office provider and the county of venue is:

c/o:
Name of Commercial Registered Office Provider — County

3. New address. *Complete part (a) or (b) – not both:*

(a) The address in this Commonwealth to which the registered office of the corporation, limited partnership or limited liability company is to be changed is:

Number and street — City — State — Zip — County

(b) The registered office of the corporation, limited partnership or limited liability company shall be provided by:

c/o: C T Corporation System — Dauphin
Name of Commercial Registered Office Provider — County

Revised 8/2013

2014 DEC -4 AM 11:34
PA. DEPT. OF STATE

DSCB:15-1507/4144/5507/5144/8506/8906-2

4. *For corporations only:*

Such change was authorized by the Board of Directors of the corporation.

IN TESTIMONY WHEREOF, the undersigned has caused this Statement or Certificate of Change of Registered Office to be signed by a duly authorized officer, general partner, member or manager thereof this

3 day of December, 2014.

Specialized Pharmaceuticals
Name of Corporation/Limited Partnership/
Limited Liability Company

Signature

Secretary
Title

Entity# : 2944023
Date Filed : 07/24/2017
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

☐ Return document by mail to:
Corporation Service Company
Name
Order No. 731516/116
Address
City State Zip Code
☑ Return document by email to: aml.casper@cscglobal.com

Change of Registered Office
DSCB:15-1507/5507/8625/8825
TC0170725DP0528

Read all instructions prior to completing. This form may be submitted online at https://www.corporations.pa.gov/.

Fee: $5 The type of domestic association (check only one):

☑ Business Corporation ☐ Limited Liability Company ☐ Limited Liability Limited Partnership
☐ Nonprofit Corporation ☐ Limited Partnership

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. § 1507/5507/8625/8825 (relating to change of registered office), the undersigned domestic corporation, limited liability company, limited partnership or limited liability limited partnership, desiring to effect a change of registered office, hereby states that:

1. The name of the association is: Specialized Pharmaceuticals, Inc.
2. The current registered office address as on file with the Department of State. *Complete part (a) OR (b) – not both:*

(a) _____
Number and street City State Zip County

(b) c/o: CT CORPORATION SYSTEM Dauphin
Name of Commercial Registered Office Provider County

3. New address. *Complete part (a) OR (b) – not both:*

(a) The address in this Commonwealth to which the registered office of the corporation, limited partnership, limited liability limited partnership or limited liability company is to be changed is:

_____
Number and street City State Zip County

(b) The registered office of the corporation, limited partnership, limited liability partnership, limited liability limited partnership or limited liability company shall be provided by:

c/o: Corporation Service Company Dauphin
Name of Commercial Registered Office Provider County

4. *For corporations only:* Such change was authorized by the Board of Directors of the corporation.

IN TESTIMONY WHEREOF, the undersigned has caused this Statement or Certificate of Change of Registered Office to be signed by a duly authorized officer, general partner, member or manager thereof this 19th day of July, 2017.

Specialized Pharmaceuticals, Inc.
Name of Corporation/Limited Partnership/
Limited Liability Limited Partnership/Limited Liability Company

Signature

JB Cilmi, Vice President
Title

2017 JUL 24 PM 2:03
PA. DEPT. OF STATE

THIRD AMENDED AND RESTATED
BY-LAWS
OF
SPECIALIZED PHARMACEUTICALS, INC.
a Pennsylvania corporation

Adopted as of: October, 17, 2016

These By-Laws are adopted by the Corporation and are supplemental to the Pennsylvania Business Corporation Law (the "PBCL") as the same shall from time to time be in effect.

ARTICLE I

IDENTIFICATION; OFFICES

SECTION 1.1 Name. The name of or the corporation is Specialized Pharmaceuticals, Inc. (the "Corporation").

SECTION 1.2 Registered Office; Other Offices. The registered office of the Corporation in the Commonwealth of Pennsylvania shall be located in the City of Harrisburg, County of Dauphin, Commonwealth of Pennsylvania. The Corporation may have such other offices, either within or without the Commonwealth of Pennsylvania, as the business of the Corporation may require from time to time.

ARTICLE II

SHAREHOLDERS

SECTION 2.1 Annual Meeting. An annual meeting of the Shareholders shall be held each year within five (5) months after the close of the fiscal year of the Corporation. At each annual meeting, the Shareholders shall elect the Directors of the Corporation as provided in Section 3.2 of these By-Laws, and may conduct any additional proper business.

SECTION 2.2 Special Meeting. A special meeting of the Shareholders may be called by the President of the Corporation, by the Chairman of the Board of Directors, or by such other officers or persons as the Board of Directors may designate.

SECTION 2.3 Place of Shareholder Meetings. The Board of Directors may designate any place, either within or without the Commonwealth of Pennsylvania, as the place of meeting for any annual meeting or for any special meeting. If no such place is designated by the Board of Directors, the place of meeting will be the principal business office of the Corporation.

SECTION 2.4 Notice of Meetings. Unless waived as herein provided, whenever Shareholders are required or permitted to take any action at a meeting, written notice of the meeting shall be given stating the place, date and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. The written notice shall be given not less than ten (10) days nor more than sixty (60) days before the date of the meeting to each Shareholder entitled to vote at the meeting or in the event of a merger,

consolidation, share exchange, dissolution or sale, lease or exchange of all or substantially all of the Corporation's property, business or assets not less than twenty (20) days before the meeting date. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the Shareholder at the Shareholder's address as it appears on the records of the Corporation.

When a meeting is adjourned to another time or place in accordance with Section 2.5 of these By-Laws, notice need not be given of the adjourned meeting if the time and place thereof are announced at the meeting in which the adjournment is taken. At the adjourned meeting the Corporation may conduct any business which might have been transacted at the original meeting. If the adjournment is for more than thirty days (30), or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each Shareholder of record entitled to vote at the meeting.

SECTION 2.5 Quorum and Adjourned Meetings. Unless otherwise provided by law or the Corporation's Articles of Incorporation, a majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at a meeting of Shareholders. If less than a majority of the shares entitled to vote at a meeting of Shareholders is present in person or represented by proxy at such meeting, a majority of the shares so represented may adjourn the meeting from time to time without further notice. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the original meeting. The Shareholders present at a meeting may continue to transact business until adjournment, notwithstanding the withdrawal of such number of Shareholders may leave less than a quorum.

SECTION 2.6 Fixing of Record Date.

(a) For the purpose of determining Shareholders entitled to notice of or to vote at any meeting of Shareholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining Shareholders entitled to notice of or to vote at a meeting of Shareholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of Shareholders of record entitled to notice of or to vote at a meeting of Shareholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

(b) For the purpose of determining Shareholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is established by the Board of Directors, and which date shall not be more than ten (10) days after the date on which the resolution fixing the record date is adopted by the Board of Directors. If no record date has been fixed by the Board of Directors, the record date for determining Shareholders entitled to consent to corporate action in writing without a meeting, when no prior action by the

Board of Directors is required by law, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in the Commonwealth of Pennsylvania, its principal office, or an officer or agent of the Corporation having custody of the book in which the proceedings of meetings of Shareholders are recorded. Delivery to the Corporation's registered office shall be by hand or by certified or registered mail, return receipt requested. If no record date has been fixed by the Board of Directors and prior action by the Board of Directors is required by law, the record date for determining Shareholders' consent to corporate action in writing without a meeting shall be the close of business on the day on which the Board of Directors adopts the resolution taking such prior action.

(c) For the purpose of determining the Shareholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the Shareholders entitled to exercise any rights in respect to any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix the record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining the Shareholders for any such purpose shall be the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

SECTION 2.7 Voting List. The officer in charge of the stock ledger of the Corporation shall prepare, at least ten (10) days prior to every meeting of Shareholders, a complete list of Shareholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each shareholder and the number of shares registered in the name of each shareholder. Such list shall be open to the examination of any Shareholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the meeting during the whole time thereof, and may be inspected by any Shareholder who is present. The stock ledger shall be the only evidence as to who are the Shareholders entitled to examine the stock ledger, the list required by this Section 2.7 or the books of the corporation or to vote in person or by proxy at any meeting of Shareholders.

SECTION 2.8 Voting. Unless otherwise provided by the Articles of Incorporation, each Shareholder shall be entitled to one (1) vote for each share of capital stock held by each Shareholder. In all matters other than the election of Directors, the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the Shareholders. Directors shall be elected by plurality of the votes of the shares present in person or represented by a proxy at the meeting entitled to vote on the election of Directors.

SECTION 2.9 Proxies. Each Shareholder entitled to vote at a meeting of Shareholders or to express consent or dissent to corporate action in writing without a meeting may vote either in person or by proxy, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. A duly executed proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with

an interest sufficient in law to support an irrevocable power. A proxy may remain irrevocable regardless of whether the interest with which it is coupled is an interest in the stock itself or an interest in the Corporation generally. Every proxy shall be in writing, subscribed by the Shareholder or his duly authorized attorney-in-fact, but need not be sealed, witnessed or acknowledged.

SECTION 2.10 **Ratification of Acts of Directors and Officers.** Except as otherwise provided by law or by the Articles of Incorporation of the Corporation, any transaction or contract or act of the Corporation or of the Directors or the officers of the Corporation may be ratified by the affirmative vote of the holders of the number of shares which would have been necessary to approve such transaction, contract or act at a meeting of Shareholders, or by the written consent of Shareholders in lieu of a meeting.

SECTION 2.11 **Written Action of Shareholders.** Any action required to be taken at any annual or special meeting of Shareholders of the Corporation, or any action which may be taken at any annual or special meeting of such Shareholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those Shareholders who have not consented in writing.

SECTION 2.12 **Organization.** Such person as the Board of Directors may designate or, in the absence of such a designation, the President of the Corporation or, in his or her absence, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present, in person or by proxy, shall call to order any meeting of the Shareholders and act as chairman of such meeting. In the absence of a Secretary of the Corporation, the chairman of the meeting shall appoint a person to serve as secretary at the meeting.

ARTICLE III

BOARD OF DIRECTORS

SECTION 3.1 **General Powers.** The business, property and affairs of the Corporation shall be managed by the Board of Directors.

SECTION 3.2 **Constitution of the Board; Rights and Powers of the Board; Meetings of the Board.**

(a) Number. The size of the Board shall be two (2) or such larger number as may be fixed from time to time by action of the Shareholders or the Board, unless otherwise specified in the Certificate of Incorporation. The current Directors are and shall continue to be as follows, with the following designees being duly elected Directors of the Company:

(i) John Figueroa; and

(ii) Victor Breed.

(b) Any Directors designed by the Board may be removed from the Board by the Shareholders, with or without cause. In the event any vacancy in the Board shall occur as a result of death, disability, resignation, removal or other termination of a Director, such vacancy may be filled by the Shareholders, and prior to such time, the corresponding vacancy in the Board shall remain vacant.

(c) Except as specifically provided otherwise in this Agreement or by non-waivable provisions of the PBCL, any action taken by the Board may only be taken with the approval, either in writing or at a duly called meeting, of Directors holding (in accordance with this Section 3.2(c)) a majority of the votes held by the Directors then serving on the Board. Each Director shall be entitled to one (1) vote on matters coming before the Board.

(d) The Board may establish one or more committees, which shall be comprised solely of Directors.

(e) Unless otherwise required by law or as approved by the Board, the composition of the Board of Directors (or body serving a similar function) of each Subsidiary of the Company, if any (each, a "Sub Board"), shall be the same as that of the Board, and the provisions of this Section 3.2 shall apply equally to each Sub Board (including as to the number of votes for Directors pursuant to Section 3.2 and the designation and replacement of Sub Board members)

(f) The Company shall reimburse each Director for all reasonable out-of-pocket expenses incurred in connection with his or her duties as a Board member or committee member.

SECTION 3.3 Meetings of Board.

(a) The Board may hold its meetings in such place or places in the State of Delaware or outside the State of Delaware as it shall determine from time to time.

(b) Meetings of the Board or a Board committee shall be held whenever called by at least two (2) Directors. Notice of the day, hour and place of holding of each meeting of the Board or any meeting of a Board committee shall be given to each Director or committee member by email or any other method under Article X, at least twenty four (24) hours before the meeting. Unless otherwise indicated in the notice thereof, any and all business may be transacted at any such meeting. At any meeting at which every Director or committee member shall be present, even though without any notice, any business may be transacted.

(c) A quorum for the transaction of business by the Board shall consist of Directors holding (in accordance with Section 3.2(c)) a majority of votes held by the Directors then serving on the Board, and a quorum for the transaction of business by a Board committee shall consist of committee members holding a majority of the votes held by the committee members then serving on such committee. If at any meeting of the Board or committee thereof, there is less than a quorum present, holders of a majority of the votes held by those present may adjourn the meeting from time to time until a quorum is present.

(d) Any Director may participate in any meeting of the Board or a Board committee by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation shall constitute

presence in person at such meeting. Any Director may participate in any meeting either in person or by proxy.

(c) Any action required or permitted to be taken at any meeting of the Board or a committee thereof may be taken without a meeting if a consent in writing, setting forth the action so taken, is signed by Directors holding (in accordance with Section 3.2(c)) a majority of the votes held by the Directors then serving on the Board or such committee. Prompt notice of the taking of an action without a meeting by less than unanimous written consent shall be given to those Directors who have not consented in writing. All such writings shall be filed with the minutes of proceedings of the Board or committee, as the case may be.

ARTICLE IV

WAIVER OF NOTICE

SECTION 4.1 Written Waiver of Notice. A written waiver of any required notice, signed by the person entitled to notice, whether before or after the date stated therein, shall be deemed equivalent to notice. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of Shareholders, Directors or members of a committee of Directors need be specified in any written waiver of notice.

SECTION 4.2 Attendance as Waiver of Notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, and objects at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

SECTION 4.3 Notice. All demands, notices, requests, consents and other communications required or permitted under this agreement shall be in writing and shall be personally delivered or sent by facsimile machine (with a confirmation copy sent by one of the other methods authorized in this section), electronic mail, reputable commercial overnight delivery service (including Federal Express and U.S. Postal Service overnight delivery service) or deposited with the U.S. Postal Service mailed first class, registered or certified mail, postage prepaid, as set forth below:

(a) If to the Company, to:

Specialized Pharmaceuticals, Inc.
18300 Cascade Avenue South, Suite 251
Tukwila, WA 98188
Attention: Victor Breed
Email: vbreed@genoa-qol.com
Facsimile: (425) 656-8200

(b) If to any other Director, to its address set forth on Schedule A.

Notices shall be deemed given and delivered upon the earlier to occur of (i) receipt by the party to whom such notice is directed; (ii) if sent by facsimile machine, on the day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) such notice

is sent if sent (as evidenced by the facsimile confirmed receipt) prior to 5:00 p.m. Eastern Time and, if sent after 5:00 p.m. Eastern Time, on the day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) after which such notice is sent; (iii) on the first day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) following the day the same is deposited with the commercial courier if sent by commercial overnight delivery service; or (iv) the fifth day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) following deposit thereof with the U.S. Postal Service as aforesaid. Each party, by notice duly given in accordance herewith, may specify a different address for the giving of any notice hereunder.

ARTICLE V

OFFICERS

SECTION 5.1 Number. The principal officers of the Corporation shall be a Chief Executive Officer, a President, a Chief Financial Officer, an Executive Vice President and a Secretary. In addition, there may be such other or subordinate officers, agents and employees as may be appointed in accordance with the provisions of Section 5.3. Any two or more offices may be held by the same person, except that if there are two or more officers of the Corporation, the office of Secretary shall be held by a person other than the person holding the office of Chief Executive Officer or President.

SECTION 5.2 Election, Qualifications and Term of Office. Each officer of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3, shall be elected annually by the Board of Directors and shall hold office until his successor shall have been duly elected and qualified, or until his death, or until he shall have resigned or shall have been removed in the manner herein provided.

SECTION 5.3 Other Officers. The Corporation may have such other officers, agents, and employees as the Board of Directors may deem necessary, including a Chairman, a Controller, one or more Assistant Controllers, a Treasurer, one or more Assistant Treasurers and one or more Assistant Secretaries, each of whom shall hold office for such period, have such authority, and perform such duties as the Board of Directors, any committee of the Board designated by it to so act, or the Chief Executive Officer, the President, the Chief Financial Officer, or the Chairman, if any, may from time to time determine. The Board of Directors may delegate to any principal officer the power to appoint or remove any such subordinate officers, agents or employees.

SECTION 5.4 Removal. Any officer may be removed, either with or without cause, by the vote of a majority of the whole Board of Directors or, except in case of any officer elected by the Board of Directors, by any committee of officers upon whom the power of removal may be conferred by the Board of Directors.

SECTION 5.5 Resignation. Any officer may resign at any time by giving written notice to the Board of Directors or the Chief Executive Officer, the President, the Chief Financial Officer, or the Chairman, if any, or the Secretary of the Corporation. Any such resignation shall take effect at the date of receipt of such notice or at any later time specified therein; and, unless

otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

SECTION 5.6 Vacancies. A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled for the unexpired portion of the term in the manner prescribed in these By-Laws for regular election or appointment to such office.

SECTION 5.7 Chairman of the Board. The Chairman of the Board, if any, shall be a director and shall preside at all meetings of the Board of Directors and shareholders. Subject to determination by the Board of Directors, the Chairman, if any, shall have general executive powers and such specific powers and duties as from time to time may be conferred or assigned by the Board of Directors.

SECTION 5.8 Chief Executive Officer. Under the direction of and, at all times, subject to the authority of the Board of Directors, the Chief Executive Officer will have general supervision over the day to day business, operations and affairs of the Corporation and will perform such duties and exercise such powers as are incident to the office of Chief Executive Officer of a corporation organized under the PBCL. The Chief Executive Officer will have such other powers and perform such other duties as may from time to time be prescribed by the Board of Directors.

SECTION 5.9 President. Under the direction of and, at all times, subject to the authority of the Board of Directors, the President of the Corporation will perform such duties and exercise such powers as are incident to the offices of president of a corporation organized under the PBCL. In the absence of the Chief Executive Officer, the President will perform the duties of the Chief Executive Officer. The President will have such other powers and perform such other duties as may from time to time be prescribed by the Board of Directors.

SECTION 5.10 Chief Financial Officer. The Chief Financial Officer will keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the Corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital and capital securities, and, in general, will perform all the duties incident to the office of the Chief Financial Officer of a corporation organized under the PBCL. The Chief Financial Officer will have the custody of the funds and securities of the Corporation, and will keep full and accurate accounts of receipts and disbursements in books belonging to the Corporation. The Chief Financial Officer will have such other powers and perform such other duties as may from time to time be prescribed by the Board of Directors, the Chief Executive Officer and/or the President.

SECTION 5.11 Secretary. The Secretary of the Corporation will (i) keep the minutes of the meetings of the Shareholders and the Board of Directors in one or more books provided for that purpose; (ii) see that all notices are duly given in accordance with the provisions of the Articles of Incorporation or these By-Laws and as required by applicable law; (iii) be custodian of the Corporation's records; (iv) keep a register of the address of each Shareholder which will be furnished to the Secretary by such Shareholder; and (v) in general perform all duties incident to the office of the Secretary of a corporation organized under the PBCL. The Secretary will

have such other powers and perform such other duties as may from time to time be prescribed by the Board of Directors, the Chief Executive Officer and/or the President.

SECTION 5.12 The Assistant Secretaries. At the request, or in the absence or disability, of the Secretary, the Assistant Secretary, if any, designated by the Secretary or the Board of Directors shall perform all the duties of the Secretary and, when so acting, shall have all the powers of the Secretary. The Assistant Secretaries shall perform such other duties as from time to time may be assigned to them by the Board of Directors or any committee of the Board designated by it so to act, or by the Chief Executive Officer and/or the President, if any, or the Secretary.

SECTION 5.13 Treasurer. The Treasurer, if any, shall have such powers and perform such duties as from time to time may be conferred upon or assigned to him by the Board of Directors or any committee of the Board designated by it to so act, or by the President and/or Chief Executive Officer.

SECTION 5.14. Salaries. The salaries of the principal officers of the Corporation shall be fixed from time to time by the Board of Directors or a special committee thereof, and none of such officers shall be prevented from receiving a salary by reason of the fact that he is a director of the Corporation.

ARTICLE VI

CERTIFICATES FOR SHARES

SECTION 6.1 Certificates of Shares. The shares of the Corporation shall be represented by certificates, provided that the Board of Directors of the Corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Notwithstanding the adoption of such a resolution by the Board of Directors, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the Corporation by the Chairman or Vice Chairman of the Board of Directors, Chief Executive Officer, or the President or Vice President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary of the Corporation representing the number of shares registered in certificate form. Any or all the signatures on the certificate may be a facsimile.

SECTION 6.2 Signatures of Former Officer, Transfer Agent or Registrar. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person or entity were such officer, transfer agent or registrar at the date of issue.

SECTION 6.3 Transfer of Shares. Transfers of shares of the Corporation shall be made only on the books of the Corporation by the holder of record thereof or by his legal representative, who shall furnish proper evidence of authority to transfer, or by his or her

attorney thereunto authorized by power of attorney duly executed and filed with an officer of the Corporation, and on surrender for cancellation of certificate for such shares. Prior to due presentment of a certificate for shares for registration of transfer, the Corporation may treat a registered owner of such shares as the person exclusively entitled to vote, to receive notifications and otherwise have and exercise all of the right and powers of an owner of shares.

SECTION 6.4 Lost, Destroyed Certificates. Whenever a certificate representing shares of the Corporation has been lost, destroyed or stolen, the holder thereof may file in the office of the Corporation an affidavit setting forth, to the best of his knowledge and belief, the time, place, and circumstance of such loss, destruction or theft together with a statement of indemnity sufficient in the opinion of the Board of Directors to indemnify the Corporation against any claim that may be made against it on amount of the alleged loss of any such certificate. Thereupon the Board may cause to be issued to such person or such person's legal representative a new certificate or duplicate of the certificate alleged to have been lost, destroyed or stolen. In the exercise of its discretion, the Board of Directors may waive the indemnification requirements provided herein.

ARTICLE VII

DIVIDENDS

SECTION 7.1 Dividends. The Board of Directors of the Corporation may declare and pay dividends upon the shares of the Corporation's capital stock in any form determined by the Board of Directors, in the manner and upon the terms and conditions provided by law.

ARTICLE VIII

CONTRACTS, LOANS, CHECKS AND DEPOSITS, INDEMNIFICATION AND FISCAL YEAR END

SECTION 8.1 Contracts. The Board of Directors may authorize any officer or officers, agent or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the Corporation, and such authority may be general or confined to specific instances.

SECTION 8.2 Loans. No loans shall be contracted on behalf of the Corporation and no evidences of indebtedness shall be issued in its name unless authorized by a resolution of the Board of Directors. Such authority may be general or confined to specific instances.

SECTION 8.3 Signatories. All checks, drafts or other orders for the payment of money, notes or other evidences of indebtedness issued in the name of the Corporation shall be signed by one (1) or more officers or agents of the Corporation and in such manner as shall from time to time be determined by resolution of the Board of Directors.

SECTION 8.4 Deposits. The funds of the Corporation may be deposited or invested in such bank account, in such investments or with such other depositaries as determined by the Board of Directors.

SECTION 8.5 Indemnification of Directors and Officers.

(a) No director of the Corporation or any other Covered Person ("QoL Covered Person") shall be liable to the Corporation or any other QoL Covered Person for any loss, damage or claim incurred by reason of any act or omission performed or omitted by such QoL Covered Person in good faith on behalf of the Corporation, its Subsidiaries or any Persons which at such time own, directly or indirectly through another Person, at least a majority of the outstanding Capital Securities of the Corporation ("Parents" and each a "Parent"), and in a manner reasonably believed to be within the scope of authority conferred on such QoL, Covered Person by these By-Laws, except that a QoL Covered Person shall not be released from liability for any such loss, damage or claim incurred by reason of such QoL Covered Person's fraud, intentional misconduct or bad faith violation of the implied contractual covenant of good faith and fair dealing, and this provision shall not reduce or limit the contractual liability of an QoL Covered Person for breach of any Related Agreement or other agreement with the Corporation or a Subsidiary or Parent to which such QoL Covered Person is a party.

(b) A QoL Covered Person shall be fully protected in relying in good faith upon the records of the Corporation and its Subsidiaries and Parents and upon such information, opinions, reports or statements presented to the Corporation and its Subsidiaries and Parents by any Person as to matters the QoL Covered Person reasonably believes are within such other Person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation and its Subsidiaries and Parents, including information, opinions, reports or statements as to the value and amount of the assets, liabilities, profits, losses or income or any other facts pertinent to the existence and amount of assets from which distributions to Corporation's stockholders might properly be paid.

(c) To the fullest extent permitted by applicable law, no QoL Covered Person shall have any duty (including any fiduciary duty or any other duty or standard of care that may arise by default principles of law) to the Corporation or any Subsidiary, Parent, stockholder, director or other Persons, provided, however, that nothing in these By-Laws eliminates the implied contractual covenant of good faith and fair dealing. Without limitation of the foregoing, whenever in these By-Laws or at law or in equity a QoL Covered Person is permitted or required to exercise such Person's discretion in acting in such capacity, including making any elections or granting, withholding or conditioning any consent, such QoL Covered Person shall be entitled to consider only such interests and factors as such QoL Covered Person elects and shall have no duty or obligation to give any consideration to any interests of or factors affecting the Corporation or any Subsidiary, Parent, stockholder, director or other Persons, or to disclose any such real, perceived or potential conflicts. The Corporation and each stockholder agree that the provisions of these By-Laws, to the extent such provisions eliminate, restrict or limit the duties (including, without limitation, fiduciary duties) or liabilities of QoL Covered Persons that may otherwise exist at law or in equity, shall replace such duties and liabilities of QoL Covered Persons to the fullest extent permitted by applicable law.

(d) The Corporation shall indemnify and hold harmless each QoL Covered Person to the fullest extent permitted by applicable law from and against any and all losses, claims, demands, costs, damages, liabilities (joint or several), expenses of any nature (including reasonable legal and accounting fees and expenses, costs of investigation and sums paid in

settlement), judgments, fines, settlements, and other amounts ("Indemnified Costs") arising from any and all claims, demands, actions, suits, or proceedings, whether civil, criminal, administrative or investigative, in which the QoL Covered Person may be involved, or threatened to be involved as a party or otherwise, incurred by reason of any act or omission performed or omitted by such QoL Covered Person in connection with matters relating to the Corporation and its Subsidiaries and Parents, and in a manner reasonably believed to be within the scope of authority conferred on such QoL Covered Person, regardless of whether the QoL Covered Person is a QoL Covered Person at the time any such Indemnified Cost is paid or incurred, except that no QoL Covered Person shall be entitled to be indemnified in respect of (and this provision shall not reduce or limit the liability of a QoL Covered Person with respect to) any Indemnified Cost incurred by such QoL Covered Person by reason of such QoL Covered Person's fraud, intentional misconduct or bad faith violation of the implied contractual covenant of good faith and fair dealing, and this provision shall not reduce or limit the contractual liability of a QoL Covered Person for breach of a Related Agreement or other agreement with the Corporation or a Subsidiary or Parent to which such QoL Covered Person is a party; provided, however, that any indemnity under this Section 8.5 shall be provided out of and to the extent of the assets of the Corporation's and its Subsidiaries', and no QoL Covered Person shall have any personal liability on account thereof. Further, the Corporation shall not indemnify any QoL Covered Person in connection with a proceeding (or part thereof) initiated by such Person against the Corporation or any Subsidiary or Parent or any other QoL Covered Person, whether by direct claim, counterclaim or otherwise, unless the initiation thereof was approved or ratified by the Board of Directors of the Corporation.

(e) The indemnification provided by this Article VIII shall be in addition to any other rights to which a QoL Covered Person may be entitled under any agreement, vote of the Board of Directors of the Corporation, as a matter of law or equity, or otherwise, both as to an action in the QoL Covered Person's capacity as a QoL Covered Person, and as to an action in another capacity, and shall continue as to a QoL Covered Person who has ceased to serve in such capacity and shall inure to the benefit of the heirs, successors, assigns, and administrators of each QoL Covered Person.

(f) Notwithstanding any other provision of this Article VIII, the Corporation shall reimburse Indemnified Costs incurred by a QoL Covered Person in connection with such Person's appearance as a witness on behalf of the Corporation or its Subsidiaries or Parents or other participation at the request of the Corporation or a Subsidiary or Parent in a proceeding involving or affecting the Corporation or its Subsidiaries or Parents at a time when the QoL Covered Person is not a named defendant or respondent in the proceeding.

(g) The Board of Directors of the Corporation shall cause the Corporation to purchase and maintain directors' and officers' insurance on behalf of the applicable QoL Covered Persons and/or the Corporation and its Subsidiaries and Parents against liabilities asserted against any such QoL Covered Person and incurred by any such QoL Covered Person in such Person's capacity as such or arising out of such QoL Covered Person's status in such capacity, regardless of whether the Corporation would have the power to indemnify the QoL Covered Person against that liability under this Article VIII, to the extent that such insurance is available on commercially reasonable terms. In furtherance of the foregoing, the Corporation shall obtain and maintain directors' and officers' liability insurance with coverage in a face amount determined

by the Board of Directors of the Corporation. The indemnification provided by this Article VIII shall be in addition to any other rights to which the QoL Covered Persons may be entitled under any agreement, vote of the Board of Directors of the Corporation, as a matter of law, or otherwise, shall continue as to a QoL Covered Person who has ceased to serve in such capacity, and shall inure to the benefit of the heirs, successors, assigns and administrators of the QoL Covered Persons.

(h) A QoL Covered Person shall not be denied indemnification in whole or in part under this Article VIII solely because the QoL Covered Person had an interest in the transaction with respect to which the indemnification applies if the transaction was otherwise permitted by the terms of any Related Agreement.

(i) To the fullest extent permitted by applicable law, the Corporation may, in the sole discretion of the Board of Directors of the Corporation, from time to time advance expenses (including reasonable legal fees and expenses, and costs of investigation) incurred by a QoL Covered Person in defending or settling any claim, demand, action, suit or proceeding prior to the final disposition of such claim, demand, action, suit or proceeding that may be subject to a right of indemnification hereunder upon receipt by the Corporation of a written undertaking by or on behalf of the QoL Covered Person to repay such amount if it shall be finally determined that the QoL Covered Person is not entitled to be indemnified as authorized in this Article VIII.

(j) (1) The rights set forth in this Article VIII are contractual in nature and may not be revised as applied to prior actions of a QoL Covered Person by a subsequent amendment of these By-Laws without such QoL Covered Person's prior written approval.

(k) For the avoidance of doubt, the exculpation, indemnification and advancement of expenses provisions set forth in Article 6 of the Amended and Restated Bylaws of the Corporation that were adopted on December 11, 2007 and that were in effect immediately prior to the SPI Effective Time (as defined in that certain Agreement and Plan of Merger, dated October 14, 2013, by and among the Corporation and the other parties thereto) shall govern the rights of the current and former directors and officers of the Corporation for any and all actions or omissions occurring prior to the SPI Effective Time. The provisions set forth in Sections 8.5(a) through 8.5(l) of these By-Laws shall govern the rights of QoL Covered Persons for any and all actions or omissions occurring at or following the SPI Effective Time.

SECTION 8.6 Fiscal Year. Except as from time to time otherwise determined by the Board of Directors, the fiscal year of the Corporation shall end on December 31.

ARTICLE IX

AMENDMENTS

SECTION 9.1 Amendments. These By-Laws may be adopted, amended or repealed by a majority vote of either the Corporation's Board of Directors or its Shareholders.

SCHEDULE A

Director Notice Information

1. If to John Figueroa:

18300 Cascade Avenue South, Suite 251
Tukwila, WA 98188
Attention: John Figueroa
Email: jfigueroa@genoa-qol.com

2. If to Victor Breed:

18300 Cascade Avenue South, Suite 251
Tukwila, WA 98188
Attention: Victor Breed
Email: vbreed@genoa-qol.com

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF STATE

06/04/2018

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

Genoa Healthcare LLC

I, Robert Torres, Acting Secretary of the Commonwealth of Pennsylvania, do hereby certify that the foregoing and annexed is a true and correct copy of

Creation Filing filed on Jul 15, 2009 - Pages (2)
Amendment filed on Dec 5, 2013 - Pages (2)
Survivor filed on Dec 5, 2013 - Pages (4)
Change of Address filed on Dec 4, 2014 - Pages (2)
Amendment filed on Jan 19, 2015 - Pages (2)
Survivor filed on Apr 30, 2015 - Pages (3)
Amendment filed on Jul 24, 2017 - Pages (1)
Amendment filed on Dec 14, 2017 Effective Dec 15, 2017 - Pages (2)
Merger filed on Feb 27, 2018 Effective Feb 28, 2018 - Pages (17)

which appear of record in this department.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Seal of the Secretary's Office to be affixed, the day and year above written

Robert Torres

Acting Secretary of the Commonwealth

Certification Number: TSC180504100450-1

Verify this certificate online at http://www.corporations.pa.gov/orders/verify

Entity #: 3893748
Date Filed: 07/15/2008
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Entity Number

Certificate of Organization
Domestic Limited Liability Company
(15 Pa.C.S. § 8913)

Name
Address — CT - COUNTER
City State Zip Code
76104718 50 fo

Document will be returned to the name and address you enter to the left.
⇐

Fee: $125

Commonwealth of Pennsylvania
CERTIFICATE OF ORGANIZATION 3 Page(s)
T0919547054

In compliance with the requirements of 15 Pa.C.S. § 8913 (relating to certificate of organization), the undersigned desiring to organize a limited liability company, hereby certifies that:

1. The name of the limited liability company *(designator is required, i.e., "company", "limited" or "limited liability company" or abbreviation)*:
QoL meds, LLC

2. The (a) address of the limited liability company's initial registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is:

(a) Number and Street	City	State	Zip	County
4900 Perry Highway, Building 2	Pittsburgh	Pennsylvania	15229	Allegheny
(b) Name of Commercial Registered Office Provider				County

3. The name and address, including street and number, if any, of each organizer is *(all organizers must sign on page 2)*:

Name	Address
Lisa M. Jaras	401 Liberty Avenue, 22nd Floor, Three Gateway Center Pittsburgh, PA 15222-1005

2008 JUL 15 PM 1:15

[CLIENT WORK\34\77\0000 E0504111.1]

DSCB:15-8913-2

4. *Strike out if inapplicable term*
~~A member's interest in the company is to be evidenced by a certificate of membership interest.~~

5. *Strike out if inapplicable:*
Management of the company is vested in a manager or managers.

6. The specified effective date, if any is: upon filing
month date year hour, if any

7. *Strike out if inapplicable:* ~~The company is a restricted professional company organized to render the following restricted professional service(s):~~

8. The term for which the Company is to exist is perpetual.

IN TESTIMONY WHEREOF, the organizer(s) has (have) signed this Certificate of Organization this

15th day of July, 2009.

Lisa M. Jaras

Lisa M. Jaras, Sole Organizer

Entity #: 3693746
Date Filed: 12/05/2013
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Certificate of Amendment-Domestic
(15 Pa.C.S.)

___ Limited Partnership (§ 8512)
__x__ Limited Liability Company (§ 8951)

Name
910469-015 KLA
Corporation Service Company

Commonwealth of Pennsylvania
LIMITED LIABILITY AMENDMENT 3 Page(s)
T1334011011

Fee: $70

In compliance with the requirements of the applicable provisions (relating to certificate of amendment), the undersigned, desiring to amend its Certificate of Limited Partnership/Organization, hereby certifies that:

1. The name of the limited partnership/limited liability company is:
QoL meds, LLC

2. The date of filing of the original Certificate of Limited Partnership/Organization: 07/15/2009

3. *Check, and if appropriate complete, one of the following:*

__x__ The amendment adopted by the limited partnership/limited liability company, set forth in full, is as follows:
Article 4 is hereby added as follows: "A member's interest in the company is to be evidenced by a certificate of membership interest."

___ The amendment adopted by the limited partnership/limited liability company is set forth in full in Exhibit A attached hereto and made a part hereof.

4. *Check, and if appropriate complete, one of the following:*

__x__ The amendment shall be effective upon filing this Certificate of Amendment in the Department of State.

___ The amendment shall be effective on: _____ (Date) at _____ (Hour)

PA DEPT. OF STATE
DEC 05 2013

DSCB:15-8512/8951-2

5. *Check if the amendment restates the Certificate of Limited Partnership/Organization:*

___ The restated Certificate of Limited Partnership/Organization supersedes the original Certificate of Limited Partnership/Organization and all previous amendments thereto.

IN TESTIMONY WHEREOF, the undersigned limited partnership/limited liability company has caused this Certificate of Amendment to be executed this

13th day of December, 2013.

QoL meds, LLC

Name of Limited Partnership/Limited Liability Company

Signature

President / CEO

Title

Entity #: 3893746
Date Filed: 12/05/2013
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Certificate of Merger or Consolidation
Limited Liability Company
(15 Pa. C.S. § 8958)

Name

910469-010 KCA
Corporation Service Company

Commonwealth of Pennsylvania
ARTICLES MERGER/CONSOLIDATION-ALL TYPES 5 Page(s)

T1334011010

Fee: $150 plus $40 additional for each party in addition to two

In compliance with the requirements of the 15 Pa.C.S. § 8958 (relating to articles of merger or consolidation), the undersigned limited liability company(s), desiring to effect a merger or consolidation, hereby state that:

1. The name of the limited liability company surviving the merger or consolidation is:
Ocl. media, LLC

2. *Check and complete one of the following:*

X The surviving limited liability company is a domestic limited liability company and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County
4900 Perry Hwy., Bldg. 2, 3rd Floor	Pittsburgh	PA	15229	Allegheny

(b) Name of Commercial Registered Office Provider — County

c/o:

___ The surviving limited liability company is a qualified foreign limited liability company formed under the laws of _____ and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street	City	State	Zip	County

(b) Name of Commercial Registered Office Provider — County

c/o:

___ The surviving limited liability company is a nonqualified foreign limited liability company formed under the laws of _____ and the address of its principal office under the laws of such domiciliary jurisdiction is:

Number and Street	City	State	Zip

DEC 05 2013

DSCB:15-8918-2

3. The name and the address of the current registered office in this Commonwealth or name of its commercial registered office provider and the county of venue of each other domestic limited liability company and qualified foreign limited liability company which is a party to the plan of merger or consolidation are as follows:

Name	Registered Office Address	Commercial Registered Office Provider	County
Ccl. Merger Sub, LLC	(DE not qualified in PA)		

4. *Check, and if appropriate complete, one of the following:*

__X__ The plan of merger or consolidation shall be effective upon filing these Articles of Merger in the Department of State.

____ The plan of merger or consolidation shall be effective on: _____ at _____
Date Hour

5. The manner in which the plan of merger or consolidation was adopted by each domestic limited liability company is as follows:

Name of Limited Liability Company	Manner of Adoption
Ccl. media, LLC	Adopted by the members and managers pursuant to 15 Pa.C.S. § 8957(g)

6. *Strike out this paragraph if no foreign limited liability company is a party to the merger or consolidation:* The plan was authorized, adopted or approved, as the case may be, by the foreign limited liability company (or each of the foreign limited liability companies) party to the plan in accordance with the laws of the jurisdiction in which it is organized.

7. *Check, and if appropriate complete, one of the following:*

____ The plan of merger or consolidation is set forth in full in Exhibit A attached hereto and made a part hereof.

__X__ Pursuant to 15 Pa.C.S. § 8958 (b) (relating to omission of certain provisions of plan of merger or consolidation) the provision, if any, of the plan of merger or consolidation that amend or constitute the operative Certificate of Organization of the surviving limited liability company as in effect subsequent to the effective date of the plan are set forth in full in Exhibit A attached hereto and made a part hereof. The full text of the plan of merger or consolidation is on file at the principal place of business of the surviving limited liability company, the address of which is:

Number and street	City	State	Zip	County
4900 Perry Hwy., Bldg. 2, 3rd Floor	Pittsburgh	PA	15229	Allegheny

DSCB: 15-8953-3

IN TESTIMONY WHEREOF, the undersigned limited liability company has caused this Certificate of Merger or Consolidation to be signed by a duly authorized member or manager thereof this

5th day of December, 2018

QOL MEDS, LLC

Name of Limited Liability Company

Signature

Chief Executive Officer

Title

QOL MERGER SUB, LLC

Name of Limited Liability Company

Signature

President

Title

DSCB: 15-8958-3

IN TESTIMONY WHEREOF, the undersigned limited liability company has caused this Certificate of Merger or Consolidation to be signed by a duly authorized member or manager thereof this

5th day of December, 2013

QOL MEDS, LLC

Name of Limited Liability Company

Signature

Chief Executive Officer

Title

QOL MERGER SUB, LLC

Name of Limited Liability Company

Signature

President

Title

Entity #: 3893749
Date Filed: 12/04/2014
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement or Certificate of Change of Registered Office (15 Pa.C.S.) for (check one):

___ Domestic Business Corporation (§ 1507)
___ Foreign Business Corporation (§ 4144)
___ Domestic Nonprofit Corporation (§ 5507)
___ Foreign Nonprofit Corporation (§ 6144)
___ Domestic Limited Partnership (§ 8506)
X Domestic Limited Liability Company (§ 8906)

Name: CT - COUNTER

Address:

City: 9364128 State: SOPA Zip Code: 50

Document will be returned to the name and address you enter to the left.

Commonwealth of Pennsylvania
DOMESTIC - CHANGE OF REGISTERED OFFICE 2 Page(s)

T1434341056

Fee: $5

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. (relating to change of registered office), the undersigned corporation, limited partnership or limited liability company, desiring to effect a change of registered office, hereby states that:

1. The name is:
QoL meds, LLC

2. Current address as registered with the Department of State. *Complete part (a) or (b) – not both:*

(a) The address of its current registered office in this Commonwealth is:

4900 Penry Highway Building 2 | Pittsburgh | PA | 15229 | Allegheny
Number and street | City | State | Zip | County

(b) The name of its current commercial registered office provider and the county of venue is:

c/o:
Name of Commercial Registered Office Provider | County

3. New address. *Complete part (a) or (b) – not both:*

(a) The address in this Commonwealth to which the registered office of the corporation, limited partnership or limited liability company is to be changed is:

Number and street | City | State | Zip | County

(b) The registered office of the corporation, limited partnership or limited liability company shall be provided by:

c/o: C T Corporation System | Dauphin
Name of Commercial Registered Office Provider | County

Revised 8/2013

2014 DEC -4 AM 11:34
PA. DEPT. OF STATE

DSCB:15-1507/4144/5307/8144/8506/8906-2

4. *For corporations only:*

Such change was authorized by the Board of Directors of the corporation.

IN TESTIMONY WHEREOF, the undersigned has caused this Statement or Certificate of Change of Registered Office to be signed by a duly authorized officer, general partner, member or manager thereof this

3 day of December, 2014.

Qol Media LLC
Name of Corporation/Limited Partnership/
Limited Liability Company

Signature

Manager
Title

Revised 8/2013

Entity #: 3933748
Date Filed: 01/13/2015
Carol Aichele
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Certificate of Amendment-Domestic
(15 Pa.C.S.)

___ Limited Partnership (§ 8512)
_x_ Limited Liability Company (§ 8951)

Name: CT - COUNTER
Address:
City: 9406034 State: 30PA Zip Code: 1

Document will be returned to the name and address you enter to the left.

Commonwealth of Pennsylvania
LIMITED LIABILITY AMENDMENT 8 Page(s)

T160136703I

Fee: $70

In compliance with the requirements of the applicable provisions (relating to certificate of amendment), the undersigned, desiring to amend its Certificate of Limited Partnership/Organization, hereby certifies that:

1. The name of the limited partnership/limited liability company is:
QoL meds, LLC

2. The date of filing of the original Certificate of Limited Partnership/Organization: July 15, 2009

3. *Check, and if appropriate complete, one of the following:*

_x_ The amendment adopted by the limited partnership/limited liability company, set forth in full, is as follows:
The name of the limited liability company be changed to: Genoa, a QoL Healthcare Company, LLC

___ The amendment adopted by the limited partnership/limited liability company is set forth in full in Exhibit A attached hereto and made a part hereof.

4. *Check, and if appropriate complete, one of the following:*

_x_ The amendment shall be effective upon filing this Certificate of Amendment in the Department of State.

___ The amendment shall be effective on: _____ (Date) at _____ (Hour).

2015 JAN 13 PM 9:30
PA. DEPT. OF STATE

DSCB:15-8512/8951-2

5. *Check if the amendment restates the Certificate of Limited Partnership/Organization:*

___ The restated Certificate of Limited Partnership/Organization supersedes the original Certificate of Limited Partnership/Organization and all previous amendments thereto.

IN TESTIMONY WHEREOF, the undersigned limited partnership/limited liability company has caused this Certificate of Amendment to be executed this

7th day of January, 2015.

Genoa, a QoL Healthcare Company, LLC
Name of Limited Partnership/Limited Liability Company

Signature

Assistant Secretary
Title

Entity #: 3583746
Date Filed: 04/30/2015
Pedro A. Cortés
Acting Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
CORPORATION BUREAU

Certificate of Merger or Consolidation
Limited Liability Company
(15 Pa. C.S. § 8958)

Commonwealth of Pennsylvania
CERTIFICATE OF MERGER 4 Page(s)

*1151297614

Name CT - COUNTER
Address
City 95336103 State SOPA Zip Code 19

Fee: $150 plus $40 additional for each party in addition to two

In compliance with the requirements of the 15 Pa.C.S. § 8958 (relating to articles of merger or consolidation), the undersigned limited liability company(s), desiring to effect a merger or consolidation, hereby state that:

1. The name of the limited liability company surviving the merger or consolidation is:
Genoa, a QoL Healthcare Company, LLC

2. *Check and complete one of the following:*

☑ The surviving limited liability company is a domestic limited liability company and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street | City | State | Zip | County

(b) Name of Commercial Registered Office Provider: c/o: CT Corporation System | County: Dauphin

☐ The surviving limited liability company is a qualified foreign limited liability company formed under the laws of _____ and the (a) address of its current registered office in this Commonwealth or (b) name of its commercial registered office provider and the county of venue is (the Department is hereby authorized to correct the following information to conform to the records of the Department):

(a) Number and Street | City | State | Zip | County

(b) Name of Commercial Registered Office Provider | County
c/o:

☐ The surviving limited liability company is a nonqualified foreign limited liability company formed under the laws of _____ and the address of its principal office under the laws of such domiciliary jurisdiction is:

Number and Street | City | State | Zip

2015 APR 30 AM 10:48
PA. DEPT. OF STATE

DSCB:15-8958-2

3. The name and the address of the current registered office in this Commonwealth or name of its commercial registered office provider and the county of venue of each other domestic limited liability company and qualified foreign limited liability company which is a party to the plan of merger or consolidation are as follows:

Name	Registered Office Address	Commercial Registered Office Provider (DB not qualified in PA)	County
Genoa Holding Company, Inc.			

4. *Check, and if appropriate complete, one of the following:*

☑ The plan of merger or consolidation shall be effective upon filing these Articles of Merger in the Department of State.

☐ The plan of merger or consolidation shall be effective on: _____ (Date) at _____ (Hour).

5. The manner in which the plan of merger or consolidation was adopted by each domestic limited liability company is as follows:

Name of Limited Liability Company	Manner of Adoption
Genoa & QoL Healthcare Company, LLC	Adopted by the members and managers pursuant to 15 Pa.C.S. § 8957(g)

6. *Strike out this paragraph if no foreign limited liability company is a party to the merger or consolidation:*

7. *Check, and if appropriate complete, one of the following:*

☐ The plan of merger or consolidation is set forth in full in Exhibit A attached hereto and made a part hereof.

☑ Pursuant to 15 Pa.C.S. § 8958 (b) (relating to omission of certain provisions of plan of merger or consolidation) the provisions, if any, of the plan of merger or consolidation that amend or constitute the operative Certificate of Organization of the surviving limited liability company as in effect subsequent to the effective date of the plan are set forth in full in Exhibit A attached hereto and made a part hereof. The full text of the plan of merger or consolidation is on file at the principal place of business of the surviving limited liability company, the address of which is:

Number and street	City	State	Zip	County
18300 Cascade Ave S #251	Tukwila	WA	98188	King

DSCR: 15-85514

IN TESTIMONY WHEREOF, the undersigned limited liability company has caused this Certificate of Merger or Consolidation to be signed by a duly authorized member or manager thereof this

30 day of April, 2015

[redacted] LLC
Name of Limited Liability Company

[redacted]
Signature

[redacted] CEO & Secretary
Title

[redacted]
Name of Limited Liability Company

[redacted]
Signature

[redacted]
Title

Entity# : 3893746
Date Filed : 07/24/2017
Pedro A. Cortés
Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

☐ Return document by mail to:
Corporation Service Company
Name
Order No. 731516/062
Address
City State Zip Code
☑ Return document by email to: aml.cas.ven@cscglobal.com

Change of Registered Office
pcro-ib-1507/5507/8625/8825
[redacted]
TC0170725DP0648

Read all instructions prior to completing. This form may be submitted online at https://www.corporations.pa.gov/.

Fee: $5 The type of domestic association (check only one):

☐ Business Corporation ☑ Limited Liability Company ☐ Limited Liability Limited Partnership
☐ Nonprofit Corporation ☐ Limited Partnership

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. § 1507/5507/8625/8825 (relating to change of registered office), the undersigned domestic corporation, limited liability company, limited partnership or limited liability limited partnership, desiring to effect a change of registered office, hereby states that:

1. The name of the association is: Genoa, a QoL Healthcare Company, LLC

2. The current registered office address as on file with the Department of State. *Complete part (a) OR (b) – not both:*

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: CT CORPORATION SYSTEM (Name of Commercial Registered Office Provider) Dauphin (County)

3. New address. *Complete part (a) OR (b) – not both:*

(a) The address in this Commonwealth to which the registered office of the corporation, limited partnership, limited liability limited partnership or limited liability company is to be changed is:

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) The registered office of the corporation, limited partnership, limited liability partnership, limited liability limited partnership or limited liability company shall be provided by:

c/o: Corporation Service Company (Name of Commercial Registered Office Provider) Dauphin (County)

4. *For corporations only:* Such change was authorized by the Board of Directors of the corporation.

IN TESTIMONY WHEREOF, the undersigned has caused this Statement or Certificate of Change of Registered Office to be signed by a duly authorized officer, general partner, member or manager thereof this 19th day of July, 20 17.

Genoa, a QoL Healthcare Company, LLC
Name of Corporation/Limited Partnership/
Limited Liability Limited Partnership/Limited Liability Company

Joel E. Comer
Signature

Jill Ciml, Attorney in Fact
Title

2017 JUL 24 PM 2:02
DEPT. OF STATE

Entity# : 3893746
Date Filed : 12/14/2017
Effective Date : 12/15/2017
Robert Torres
Acting Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

☐ Return document by mail to:
CSC order #9543602-5 WJ
Name

CSC

(x)Return document by email to: cscpa@cscglobal.com

Certificate of Amendment - Domestic Limited Partnership/Limited Liability Company

TC0171214.DM0244

Read all instructions prior to completing. This form may be submitted online at http://www.corporations.state.pa.us/

Fee: $70

Check one: ☐ Limited Partnership (§ 8622) ☒ Limited Liability Company (§ 8822)

In compliance with the requirements of the applicable provisions (relating to Amendment or Restatement of Certificate), the undersigned, desiring to amend or restate its Certificate of Limited Partnership/Certificate of Organization, hereby certifies that:

1. The name of the limited partnership/limited liability company is: Genoa, a QoL Healthcare Company, LLC

2. The date of filing of the original Certificate of Limited Partnership/Certificate of Organization is:

07/15/2009
Date (MM/DD/YYYY)

3. The current registered office address as on file with the Department of State. *Complete part (a) OR (b) – not both:*

(a) _____
Number and street City State Zip County

(b) c/o: Corporation Service Company Dauphin
Name of Commercial Registered Office Provider County

4. *Check, and if appropriate complete, one of the following:*

☒ The amendment adopted by the limited partnership/limited liability company, set forth in full, is as follows:

Name of the limited liability company: Genoa Healthcare LLC

☐ The amendment adopted by the limited partnership/limited liability company is set forth in full in Exhibit A attached hereto and made a part hereof.

5. Effective date of amendment (*check, and if appropriate complete, one of the following):*

☐ The amendment shall be effective upon filing this Certificate of Amendment in the Department of State.
☒ The amendment shall be effective on: 12/15/2017 at _____.
Date (MM/DD/YYYY) Hour (If any)

2017 DEC 14 AM 9:40
PA. DEPT. OF STATE

DSCB:15-8622/8822-2

6. *Check if the amendment restates the Certificate of Limited Partnership/Certificate of Organization:*

☐ The restated Certificate of Limited Partnership/Certificate of Organization supersedes the original Certificate of Limited Partnership/Certificate of Organization and all previous amendments thereto.

IN TESTIMONY WHEREOF, the undersigned limited partnership/limited liability company has caused this Certificate of Amendment to be executed by a duly authorized person thereof this 13th day of December, 20 17.

Genoa, a QoL Healthcare Company, LLC
Name of Limited Partnership/Limited Liability Company

Signature

Member
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy EM LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other _____

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 16300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th **day of** February, **20**18.

Advanced Care Pharmacy EM LLC
Name of Merging Association

[signature]
Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy NEGC LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: _____ (Name of Commercial Registered Office Provider) _____ (County)

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 281 18300 Cascade Avenue S. Tukwila, WA 98188
(Number and street) (City) (State) (Zip)

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

Advanced Care Pharmacy NEGC LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger – Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy Services - Genesee LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2016.

Advanced Care Pharmacy Services - Genesee LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy Services - Port Huron LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: _____ (Name of Commercial Registered Office Provider) _____ (County)

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 261 18300 Cascade Avenue S. Tukwila, WA 98188
(Number and street) (City) (State) (Zip)

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

Advanced Care Pharmacy Services - Port Huron LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum
DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy Services - Saginaw, LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):
   - ☐ Business Corporation
   - ☐ Nonprofit Corporation
   - ☒ Limited Liability Company
   - ☐ Limited Partnership
   - ☐ Limited Liability (General) Partnership
   - ☐ Limited Liability Limited Partnership
   - ☐ Business Trust
   - ☐ Professional Association
   - ☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: _____ (Name of Commercial Registered Office Provider) _____ (County)

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
(Number and street) (City) (State) (Zip)

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2016.

Advanced Care Pharmacy Services - Saginaw, LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Group Med Inc.

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☒ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☐ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

Group Med Inc.
Name of Merging Association

[signature]
Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: HDI Pharmacy Services Inc.

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☒ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☐ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 26th **day of** February, 2018.

HDI Pharmacy Services Inc.
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Tricare Pharmacy Inc.

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☒ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☐ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 26th **day of** February, 2016.

Tricare Pharmacy Inc.
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Draco Holdings LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both.

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

Draco Holdings LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: Advanced Care Pharmacy Services LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other _____

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th **day of** February, 2018.

Advanced Care Pharmacy Services LLC
Name of Merging Association

Signature

Authorized Representative
Title

Entity# : 3893748
Date Filed : 02/27/2018
Effective Date : 02/28/2018
Robert Torres
Acting Secretary of the Commonwealth

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

☐ Return document by mail to:
CSC order #708239-10 (BH
Name

CSC

(or)Return document by email to: cscpa@cscglobal.com

Statement of Merger
DSCB:15-335
(7/1/2015)

TC01802270U21294

Read all instructions prior to

Fee: $70 plus $40 for *each* association that is a party to the merger
The minimum amount to be submitted with this filing is $150

In compliance with the requirements of the applicable provisions of 15 Pa.C.S. § 335 (relating to Statement of merger), the undersigned, desiring to effect a merger, hereby states that:

A. For the surviving association:

1. The name of the surviving association is: Genoa Healthcare LLC

2. The jurisdiction of formation of the surviving association: Pennsylvania

3. The type of association of the surviving association is (check only one):

- ☐ Business Corporation
- ☐ Nonprofit Corporation
- ☑ Limited Liability Company
- ☐ Limited Partnership
- ☐ Limited Liability (General) Partnership
- ☐ Limited Liability Limited Partnership
- ☐ Business Trust
- ☐ Professional Association
- ☐ Other ____

2018 FEB 27 PM 1:23
PA. DEPT. OF STATE

DSCB:15-335-2

4. The surviving association is a (check only one box, provide address and follow instructions for attachments):

☑ Domestic (Pennsylvania) filing entity already in existence on Department of State records
If applicable, attach to this Statement any amendment to its public organic record approved as part of the plan of merger.

☐ NEW domestic (Pennsylvania) filing entity (includes limited liability limited partnership)
Attach to this Statement the public organic record of the new entity.

☐ Foreign filing association or foreign limited liability partnership already registered with the Department.
If applicable, attach to this Statement any amendment to or transfer of its foreign registration approved as part of the plan of merger.

☐ Foreign filing association or foreign limited liability partnership simultaneously seeking registration with the Department of State
Attach to this Statement a completed form DSCB:15-412 (Foreign Registration Statement) with applicable fee and attachments.

Its current registered office address. *Complete part (a) OR (b) – not both:*

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: CORPORATION SERVICE COMPANY (Name of Commercial Registered Office Provider) Dauphin (County)

☐ NEW domestic (Pennsylvania) limited liability partnership or electing partnership
Attach completed DSCB:15-8201 (Statement of Registration) or DSCB:15-8701A (Statement of Election)

☐ Domestic association that is not a domestic filing association
Attach to this Statement tax clearance certificates.

The address, including street and number, if any, of its principal office:

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

☐ Foreign association that is not, and will not, be registered with the Department of State
Attach to this Statement tax clearance certificates.

The address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office:

_____ (Number and street) _____ (City) _____ (State) _____ (Zip)

DSCB:15-335-3

B. For the merging association(s) that are not surviving the merger:

1. The name of the merging association is: Advanced Care Pharmacy Services - Saginaw LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☑ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.** *Complete part (a) OR (b) – not both:*

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☑ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

Use Statement of Merger – Addendum (DSCB:15-335AD) for additional merging parties that are not surviving the merger.

DSCB:15-335-4

C. Effective date of statement of merger (check, and if appropriate complete, one of the following):
- ☐ This Statement of Merger shall be effective upon filing in the Department of State.
- ☑ This Statement of Merger shall be effective on: 02/28/2018 (Date (MM/DD/YYYY)) at _____ (Hour (if any)).

D. Approval of merger by merging associations (check all applicable statement(s)):
- ☑ For domestic entities – The merger was approved in accordance with 15 Pa.C.S. Chapter 3, Subchapter C (relating to merger).
- ☑ For foreign associations – The merger was approved in accordance with the laws of the jurisdiction of formation.
- ☐ For domestic associations that are not domestic entities – The merger was approved by the interest holders of the merging association in the manner required by its organic law.

E. Attachments (see instructions for required and optional attachments).

IN TESTIMONY WHEREOF, the undersigned merging associations have caused this Statement of Merger to be signed by duly authorized officers thereof this 28th day of February, 2018.

Genoa Healthcare LLC	Advanced Care Pharmacy Services - Saginaw LLC
Name of Merging Association	Name of Merging Association
[signature]	[signature]
Signature	Signature
Authorized Representative	Authorized Representative
Title	Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: ACPS - Detroit LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.
Complete part (a) OR (b) – not both:

☐ (a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 26th day of February, 2018.

ACPS - Detroit LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum
DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: ACPS - New Center LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

(b) c/o: _____ (Name of Commercial Registered Office Provider) _____ (County)

☐ **If the merging association is a domestic association that *is not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____ (Number and street) _____ (City) _____ (State) _____ (Zip) _____ (County)

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 16300 Cascade Avenue S. Tukwila, WA 98188
Number and street — City — State — Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

ACPS - New Center LLC
Name of Merging Association

Signature

Authorized Representative
Title

PENNSYLVANIA DEPARTMENT OF STATE
BUREAU OF CORPORATIONS AND CHARITABLE ORGANIZATIONS

Statement of Merger - Addendum

DSCB:15-335AD
(7/1/2015)

335Ad

This form is used to identify additional merging parties and must be submitted with the Statement of Merger form (DSCB:15-335).

B. For the merging association(s) that are not surviving the merger (continued):

1. The name of the merging association is: ACPS - Waterford LLC

2. The jurisdiction of formation of the merging association: MI

3. The type of association is (check only one):

☐ Business Corporation	☐ Limited Partnership	☐ Business Trust
☐ Nonprofit Corporation	☐ Limited Liability (General) Partnership	☐ Professional Association
☒ Limited Liability Company	☐ Limited Liability Limited Partnership	☐ Other

4. Check and complete one of the following addresses.

☐ **If the merging association is a domestic filing association, domestic limited liability partnership or registered foreign association, the current registered office address as on file with the Department of State.**
Complete part (a) OR (b) – not both:

(a) _____
Number and street | City | State | Zip | County

(b) c/o: _____
Name of Commercial Registered Office Provider | County

☐ **If the merging association is a domestic association that is *not* a domestic filing association or limited liability partnership, the address, including street and number, if any, of its principal office:**

_____
Number and street | City | State | Zip | County

☒ **If the merging association is a nonregistered foreign association, the address, including street and number, if any, of its registered or similar office, if any, required to be maintained by the law of its jurisdiction of formation; or if it is not required to maintain a registered or similar office, its principal office address:**

Suite 251 18300 Cascade Avenue S. Tukwila, WA 98188
Number and street | City | State | Zip

IN TESTIMONY WHEREOF, the undersigned association has caused this Statement of Merger-Addendum to be signed by an authorized officer thereof this 28th day of February, 2018.

ACPS - Waterford LLC
Name of Merging Association

Signature

Authorized Representative
Title

ASSIGNMENT AND ASSUMPTION OF LEASE AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION OF LEASE AGREEMENT, dated for reference purposes only as of May 26, 2021 (this "Agreement"), is by and between United HealthCare Services, Inc., as assignor ("Assignor"), and Genoa Healthcare, LLC, as assignee ("Assignee").

RECITALS

WHEREAS, 701 Medical, LLC, as landlord ("Landlord"), and Assignor, as tenant, are parties to that certain Standard Office Lease Agreement, dated November 6, 2019 (as the same may have been amended from time-to-time, the "Lease"), for the Premises in the Building located at 701 Shadow Lane, Las Vegas, NV 89106; and

WHEREAS, Assignor desires to assign to Assignee, and Assignee desires to assume from Assignor, all of Assignor's rights, titles and interests in, to and under the Lease pursuant to this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

AGREEMENT

1. Defined Terms. Terms capitalized in this Agreement, but not otherwise defined, have the meanings given to them in the Lease.

2. Assignment and Assumption. Assignor hereby assigns to Assignee, and Assignee hereby assumes from Assignor, all of Assignor's rights, titles and interest, in, to and under the Lease as of August 1, 2021 (the "Effective Date"). Assignee agrees to perform all of Assignor's obligations under the Lease arising from and after the Effective Date. Assignee hereby assigns to Assignor any security deposit held by Landlord under the Lease.

3. Premises Address. The address of the Premises is 701 Shadow Lane, Suite 110, Las Vegas, NV 89106.

4. Tenant's Notices. From and after the Effective Date, all notices to be given to the Tenant under the Lease shall be sent to Assignee's attention at the following address:

Genoa Healthcare, LLC
Attn: General Counsel
707 South Grady Way, Suite 700
Renton, WA 98057

5. Miscellaneous. This Agreement is binding on the parties' successors and assigns. This Agreement may be executed in any number of counterparts, all of which are considered one and the same Agreement notwithstanding that all parties hereto have not signed the same counterpart. Signatures of this Agreement which are transmitted by either or both electronic or telephonic means (including, without limitation, .pdf and DocuSign) are valid for all purposes. Any party shall, however, deliver an original signature of this Agreement to the other party upon request.

[The balance of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first set forth above.

ASSIGNOR	ASSIGNEE
United HealthCare Services, Inc.	Genoa Healthcare, LLC
By: Adam Wilford (May 25, 2021 13:47 CDT) Name: Adam Wilford Title: Vice President, Real Estate	By: Christy Barr Name: Christy Barr Title: SVP, Pharmacy Operations

9E

RECEIVED
10/27/2020

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ Ownership Change (Provide current license number if making changes: PH IA02919
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: The Desert Hope Center

Physical Address: 2465 E. Twain Ave

City: Las Vegas State: NV Zip Code: 89121 Telephone: (702) 903-4304

Fax: 702-789-6197 Toll Free Number: _____

E-mail: _____

Website: deserthopetreatment.com

Managing Pharmacist: Nathan Connolly License Number: ~~IA02919~~ 18540 EX 10/31/21

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☑	☐ Hospital (# beds 148)	☐	☑ Parenteral
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☐	☑ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding
	For the application to be complete	☐	☑ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No X

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No X

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No X

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No X

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No X

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Dawn McCallum
Print Name of Authorized Person

10/20/2020
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: AAC New HoldCo, Inc.

Mailing Address: 200 Powell Place

City: Brentwood State: TN Zip: 37027

Telephone: (973) 383-6300 Fax: _____

Contact Person: Karen Abbott; (615) 732-1485

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

Note: American Addiction Centers, Inc. (contact information above) owns 100% LLC interest of The Desert Hope Center.

a) _____
Name Business Address

b) No Individual stockholders
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

List any physician shareholders and percentage of ownership.

Name: None %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 6 am 2 pm

Saturday 7-11 am _____ pm

Sunday 7-11 am _____ pm

24 Hours Pharmacist always on call if needed.

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20121041065

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Dawn McCallum

Responsible Person of Desert Hope Center

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Dawn McCallum
Print Name of Authorized Person

10/20/2022
Date

Managing Pharmacist

Pharmacist Name: Nathen D. Connolly License #: 18540

Pharmacy Name: Desert Hope Treatment Center

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☒
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☒
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.



Signature

10/20/2020

Date

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **AMERICAN ADDICTION CENTERS, INC.**, as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 02/27/2007, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/22/2021.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202104221612140
You may verify this certificate online at http://www.nvsos.gov

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date 4/14/21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of Pharmacy or Wholesaler

Desert Hope Treatment Center 2465 E. Twain Ave. Las Vegas, NV 89121
Name and Address of Business for Which Designated Representative Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Connolly — Last Name
Nathan — First Name
D. — Middle Name

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Dalle Valley St. — Present Residence Address-Street or RFD
North Las Vegas — City
NV 89031 — State/Zip

2465 E. Twain Ave — Present Business Address
4-23-18 to present — Dates
Las Vegas — City
NV 89121 — State/Zip

Director of Pharmacy — Present Position with the Pharmacy or Wholesaler
4-23-18 to present — Dates
Phone: Residence [redacted]
Business 702-789-6260

[redacted] — Date of Birth
Springerville, Apache, Arizona — Place of Birth (City, County, State)

37 — Age
[redacted] — Social Security Number or ITIN
Male — Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Brown	White	270 lb	Heavy	6'0"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No — If alien, registration No _____

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single — (Married) — Separated — Divorced — Widowed — Engaged

Applicant's initial N

MARITAL INFORMATION-Continued

A. **Current Marriage** 7/17/2004 (Date) Las Vegas, Clark, Nevada (City, County and State)

Spouse's full name (Maiden) Jami-Lynn Stanley SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth Salt Lake City, Salt Lake County, Utah

Resident address [redacted] (Street) Dalle Valley St. (City) North Las Vegas (State) NV (Zip) 89031

Telephone: Residence [redacted] Business N/A

Spouse's employer N/A Occupation Home Maker

Address of employer N/A (Street) (City) (State) (Zip)

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
	N/A			

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
	N/A				

3. **FAMILY INFORMATION:**

A. **Children and Dependents**:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Abbigail Lynn Connolly	[redacted]	LAs Vegas Nevada	[redacted] Dalle Valley NLV, NV 89031
Colton Nathan Connolly	[redacted]	Las Vegas Nevada	[redacted] Dalle Valley NLV, NV 89031
Hunter James Connolly	[redacted]	Las Vegas Nevada	[redacted] Dalle Valley NLV, NV 89031

B. **Child Support Information:**

Please mark the appropriate response:

✓ ▬ I am not subject to a court order for the support of child.

▬ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

▬ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial [redacted]

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Irven Dale Connolly	[redacted]	[redacted] Serena Springs St. NLV NV 89081	Cable Technitian
Mother	Margaret Gellissen	[redacted]	[redacted] Serena Springs St NLV NV 89081	Home Maker
Father-in-Law	Stephen Leroy Staley	[redacted]	[redacted] Tower Stone St. NLV NV 89084	Construction
Mother-in-Law	Janet Renae Roberts	Deceased		N/A

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
Spouse	Stephanie Ann Connolly N/A	[redacted]	[redacted] Whirlwind AVE Pahrump NV 89040	Law Enforcement
Spouse	Celestia Lynn Connolly Carlin Deloy Abbott	[redacted]	[redacted] E 450N APT 101F St. George UT 84790	Home Maker Plumber
Spouse	Timothy Ethan Connolly N/A	[redacted]	[redacted] Serena Springs NLV NV 89081	Student
Spouse	Kayal James Connolly N/A	[redacted]	[redacted] Serena Springs NLV NV 89081	Student

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Rand Valley Grade school	Eagar AZ	1988 - 1997	Yes / No
High School	Mojave Highschool	North Las Vegas NV	1998 - 2002	Yes / No
College University	Roseman University	Henderson NV	2010 2013	Yes / No
Other	N/A		N/A	Yes / No

Type of degree obtained, if any PHARM D.

College or university where obtained Roseman University

Applicant's initial M

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ~~No~~ No

Branch N/A Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ~~No~~ No If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes No

County Clark State Nevada Date registered 9-26-2001

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ~~No~~ No If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ~~No~~ No If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ~~No~~ No

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ~~No~~ No

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ~~No~~ No

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ~~No~~ No
If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ~~No~~ No
If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ~~No~~ No
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial M

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes — (No) — (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes — (No) — If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
6/14 to 4/21	[redacted] Dalle Valley	NLV	NV
11/08 to 6/14	4646 Sergeant ct	NLV	NV
10/07 to 11/8	1604 Water Creek	NLV	NV
7/06 to 10/07	3940 N Scott Robinson	NLV	NV
7/05 to 7/06	3300 N Tenaya	Las Vegas	NV
1/05 to 7/05	5045 Diamond Ranch	LV	NV
7/04 to 1/05	4429 Lawrence St.	NLV	NV
3/1995 to 7/04	5128 Vista Del Rancho	NLV	NV

Applicant's initial M

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
4/2018	Desert Hope 2665 E. Twain Ave 89121 LV, NV	6,240
Title	**Description of Duties**	**Name of Supervisor**
Director of Pharmacy	Manage Pharmacy	Brian Bulfer

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
5/2019	Costco Pharmacy 6555 N Decatur Blvd.	2,000
Title	**Description of Duties**	**Name of Supervisor**
Pharmacist	Manage Pharmacy operations	Rita Singh

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial_____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Veronica Walters	Home [redacted]	Radiant Ruby Ave	Las,	89143	(702) [redacted]	8
Employer Desert Parkway Behavioral	Business 3247 S. Maryland Pkwy, LV NV			89121		
Name Mike Morgan	Home [redacted]	Spyglass Hill Syracuse, UT,		84075	[redacted]	17 years
Employer Case, Love, & Hart INC	Business 2484 Washington Blvd #510 Ogden, UT.			84401		
Name Adam Schmidt	Home [redacted] Leaflet AVE Spring TX 77388				[redacted]	27 years
Employer Targa Resources	Business 16514 De Zavalla RD Channelview, TX 77530					5 years
Name Laura Fobin	Home [redacted] Pallman Dr Sparks NV 89434					
Employer Reno Behavioral Healthcare Hospital	Business 6940 Sierra Center Pkwy Reno NV 89511					
Name Asif Anwari	Home [redacted] Medal Park Ave. Henderson NV 89052.					5 years
Employer Desert Parkway Behavioral Health	Business 3247 S. Maryland Pkwy. LV NV 89121					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes → (No) ←

If yes, state type, where and years held

.....

.....

.....

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes → (No) ←
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

.....

.....

.....

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? (Yes) → No ←

Nevada Board of Pharmacy to open a new pharmacy at Desert Hope

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes → (No) ←

.....

If yes to the above, state where, when and for what reason:

.....

.....

Applicant's initial NC

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes No

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes No

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes No

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes No

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes No

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes No

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes No

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes No

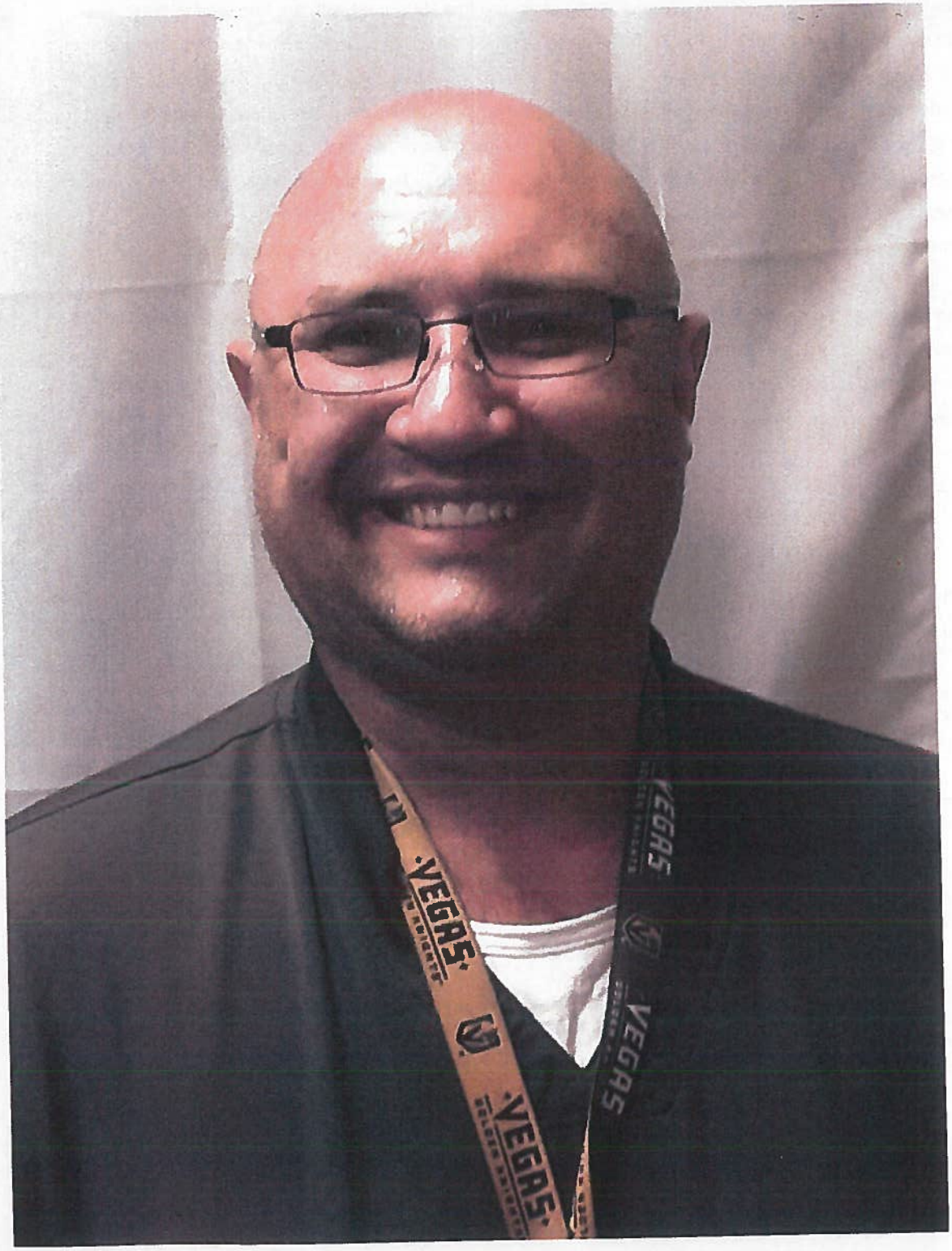
ATTACH PHOTOGRAPH

TAKEN WITHIN LAST

30 DAYS HERE

Date of photograph 4/16/2021

Applicant's initial M


VEGAS
VEGAS
VEGAS
VEGAS

STATE OF Nevada

ss.

COUNTY OF Clark

I, Brittany Noel Krempp, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 16 day of

April 2021

Notary Public

Commission Exp. 10-3-2023

(Seal) BRITTANY KREMPP
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 19-6760-01
MY APPT. EXPIRES OCTOBER 03, 2023

Applicant's initial BK

ADDITIONAL INFORMATION

Continuation of children / Dependants

Allison Melody Connolly [redacted] Las Vegas NV [redacted] Dalle Valley NV 89031

Gavin Dallen Connolly [redacted] Las Vegas NV [redacted] Dalle Valley NV 89031

Applicant's initial M

2081

List of Owners

The following entities will hold ultimate beneficial ownership in the licensed entity. The corporate organizational structure between the licensed entity and these ultimate owners is still yet to be finalized. As shown on the attached post-closing organizational chart, the ultimate beneficial owners will either hold their ownership interest in: (1) an existing entity, AAC Holdings, Inc.; or (2) one or more newly-formed holding companies that together will acquire all of the assets of AAC Holdings, Inc., including the equity interests in all of its currently-owned subsidiaries. Information regarding the final structure and any intervening holding companies will be provided as soon as it is available; as noted on the organizational chart, it is not intended that there will be any changes to the organizational structure of American Addiction Centers, Inc. or the licensed entity, Concorde Treatment Center, LLC d/b/a Desert Hope Center. Each of the following beneficial owners are passive investment funds that do not direct the day-to-day operations of the licensed entity.

Name	Address	EIN	Owner Type	Percentage of Indirect Ownership[1]
Funds Managed by Brightwood Capital Advisors, LLC with Indirect Ownership (24% in the aggregate)				
Brightwood Capital Offshore Fund IV Holdings, SPV-2, LLC	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Liability Company	0.8%
BCOF Capital, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	1.2%
Brightwood Capital Co-Invest Fund, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	0.2%
Brightwood Capital Fund III Holdings SPV-2, LLC	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Liability Company	2.3%
Brightwood Capital Fund III Holdings, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	3.4%

[1] Ownership percentages have been rounded to the nearest tenth of a percentage.

2082

Name	Address	EIN	Owner Type	Percentage of Indirect Ownership[1]
Brightwood Capital Fund III-U, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	0.2%
Brightwood Capital Fund IV Holdings SPV-2, LLC	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Liability Company	3.2%
Brightwood Capital Fund IV-U, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	1.2%
Brightwood Capital Fund IV, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	6.6%
Brightwood Capital Offshore Fund IV, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	2.0%
Brightwood Capital Offshore Fund IV-U, LP	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Partnership	0.4%
Brightwood Fund III Static 2018-1, LLC	c/o Brightwood Capital Advisors 810 Seventh Avenue, 26th Floor New York, NY 10019		Limited Liability Company	2.7%
Funds Managed by HG Vora Capital Management, LLC with Indirect Ownership (19.6% in the aggregate)				
HG Vora Special Opportunities Fund LP	c/o HG Vora Capital Management, LLC 330 Madison Avenue, 20th FL New York, NY 10017	26-4369943	Limited Partnership	8.3%
KAT SPV, LLC	c/o HG Vora Capital Management, LLC 330 Madison Avenue, 20th FL	85-3104394	Limited Liability Company	11.3%

Name	Address	EIN	Owner Type	Percentage of Indirect Ownership[1]
	New York, NY 10017			
Funds Managed by CQS (UK) LLP with Indirect Ownership (13.4% in the aggregate)				
CQS Aiguille du Chardonnet MF S.C.A. SICAV-SIF	c/o CQS (UK) LLP 4th Floor, One Strand London, England WC2N 5HR	n/a	Investment Fund	1.4%
CQS Credit Multi Asset Fund, a sub fund of CQS Global Funds (Ireland) plc	c/o CQS (UK) LLP 4th Floor, One Strand London, England WC2N 5HR	n/a	Investment Fund	9.9%
CQS Dedicated Multi Strategy Fund Limited	c/o CQS (UK) LLP 4th Floor, One Strand London, England WC2N 5HR	n/a	Investment Fund	0.5%
Gracechurch Opportunities Fund Limited	c/o CQS (UK) LLP 4th Floor, One Strand London, England WC2N 5HR	n/a	Investment Fund	1.6%
Funds Managed by Main Street Capital Corporation with Indirect Ownership (9.4% in the aggregate)				
Main Street Capital Corporation	1300 Post Oak Blvd., Suite 800 Houston, Texas 77056	41-2230745	Corporation	3.9%
HMS Equity Holding, LLC	2800 Post Oak Blvd. Ste 4800 Houston, TX 77056	32-0437065	Limited Liability Company	5.5%
Funds Managed by Capital Southwest Corporation with Indirect Ownership (6.3% in the aggregate)				
Capital Southwest Corporation	5400 LBJ Freeway, Suite 1300 Dallas, TX 75240	75-1072796	Corporation	3.5%

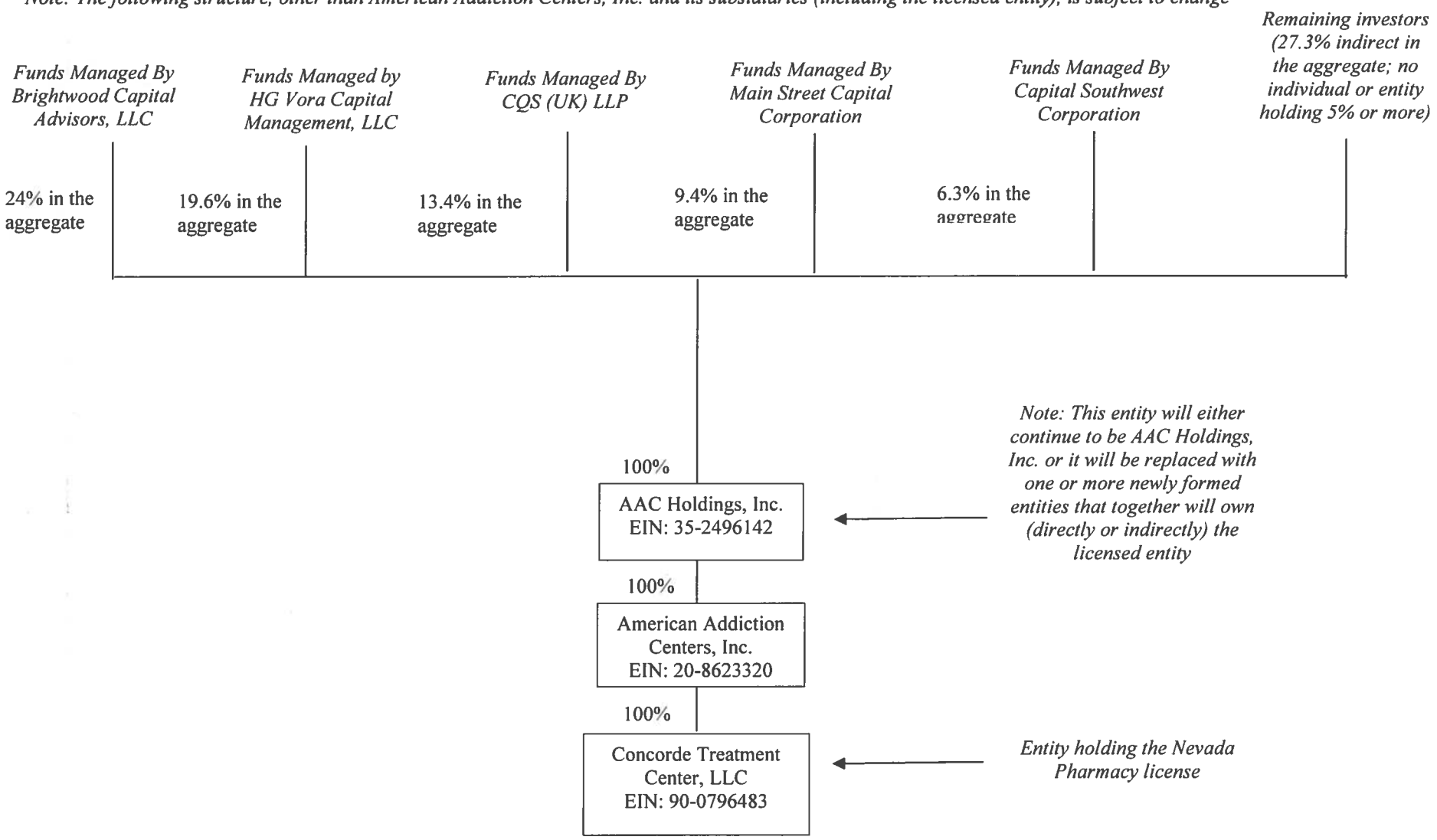
2084

Name	Address	EIN	Owner Type	Percentage of Indirect Ownership[1]
I-45 SPV LLC	5400 LBJ Freeway, Suite 1300 Dallas, TX 75240	47-4981644	Limited Liability Company	2.8%

The remainder of the indirect ownership interests (approximately 27.3% in the aggregate) are held by 47 different entities, each of which holds less than 5% indirect ownership. The majority of these funds hold less than 1% indirect interest each.

Anticipated Post-Closing Ownership Structure

Note: The following structure, other than American Addiction Centers, Inc. and its subsidiaries (including the licensed entity), is subject to change



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF FACT

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of documents on file in this office for

AMERICAN ADDICTION CENTERS, INC.

Organizational Documents on File	Filing Date
Annual List	01/07/2020
Annual List	02/25/2019
Annual List	01/24/2018
Annual List	12/16/2016
Annual List	02/02/2016
Annual List	01/13/2015
Amended List	02/18/2014
Annual List	12/04/2013
Withdrawal of Designation	03/11/2013
Annual List	02/08/2013
Noncommercial Registered Agent-Statement of Change	10/15/2012
Certificate Pursuant to NRS 78.209	08/24/2012
Amended List	05/14/2012
Annual List	03/06/2012
Amended List	07/06/2011
Amended and Restated Articles	07/05/2011
Withdrawal of Designation	06/24/2011

SECRETARY OF STATE

STATE OF NEVADA

Withdrawal of Designation	06/16/2011
Certificate of Designation	05/25/2011
Certificate of Designation	05/25/2011
Noncommercial Registered Agent-Statement of Change	04/15/2011
Annual List	01/18/2011
Annual List	04/16/2010
Annual List	02/11/2009
Amended and Restated Articles	07/31/2008
Annual List	03/18/2008
Certificate of Designation	11/02/2007
Initial List	06/14/2007
Amended and Restated Articles	06/12/2007

Certificate Number: B20200325682925
You may verify this certificate online at http://www.nvsos.gov

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 03/25/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State



ROSS MILLER
Secretary of State
204 North Carson Street, Suite 4
Carson City, Nevada 89701-4520
(775) 684-5708
Website: www.nvsos.gov

040104

Filed in the office of	Document Number
Ross Miller Secretary of State State of Nevada	20140104480-14
	Filing Date and Time 02/12/2014 8:00 AM
	Entity Number E0074682014-8

Articles of Incorporation
(PURSUANT TO NRS CHAPTER 78)

USE BLACK INK ONLY - DO NOT HIGHLIGHT — ABOVE SPACE IS FOR OFFICE USE ONLY

1. Name of Corporation: AAC Holdings, Inc.

2. Registered Agent for Service of Process: (check only one box)

☒ Commercial Registered Agent: Registered Agent Solutions, Inc. (Name)

☐ Noncommercial Registered Agent (name and address below) OR ☐ Office or Position with Entity (name and address below)

Name of Noncommercial Registered Agent OR Name of Title of Office or Other Position with Entity

Street Address — City — Nevada — Zip Code

Mailing Address (if different from street address) — City — Nevada — Zip Code

3. Authorized Stock: (number of shares corporation is authorized to issue)

Number of shares with par value: 75,000,000 — Par value per share: $ .001 — Number of shares without par value: 0

4. Names and Addresses of the Board of Directors/Trustees: (each Director/Trustee must be a natural person at least 18 years of age; attach additional page if more than two directors/trustees)

1) Michael T. Cartwright (Name)
115 East Park Drive, Second Floor — Brentwood — TN — 37027
(Street Address — City — State — Zip Code)

2) Jerrod N. Menz (Name)
115 East Park Drive, Second Floor — Brentwood — TN — 37027
(Street Address — City — State — Zip Code)

5. Purpose: (optional; required only if Benefit Corporation status selected)

The purpose of the corporation shall be:
The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Nevada Revised Statutes.

6. Benefit Corporation: (see instructions) ☐ Yes

7. Name, Address and Signature of Incorporator: (attach additional page if more than one incorporator)

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

Kathryn Sevier Phillips (Name)
X Kathryn S. Phillips (Incorporator Signature)
115 East Park Drive, Second Floor — Brentwood — TN — 37027
(Address — City — State — Zip Code)

8. Certificate of Acceptance of Appointment of Registered Agent:

I hereby accept appointment as Registered Agent for the above named Entity.

X Jaclyn Wright Asst. Secretary — February 12, 2014
(Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity — Date)

This form must be accompanied by appropriate fees.

Nevada Secretary of State NRS 78 Articles
Revised 11-13-13

ARTICLES OF INCORPORATION

OF

AAC HOLDINGS, INC.

4. Names and Addresses of the Board of Directors/Trustees: (continued)

NAME	ADDRESS
Lucius E. Burch, III	115 East Park Drive, Second Floor, Brentwood, TN 37027
David C. Kloeppel	115 East Park Drive, Second Floor, Brentwood, TN 37027
Richard E. Ragsdale	115 East Park Drive, Second Floor, Brentwood, TN 37027
Darrell S. Freeman, Sr.	115 East Park Drive, Second Floor, Brentwood, TN 37027
Jerry Bostelman	115 East Park Drive, Second Floor, Brentwood, TN 37027

ARTICLES OF INCORPORATION
OF
AAC HOLDINGS, INC.

Pursuant to the provisions of Section 78.030 of the Nevada Revised Statutes, the undersigned adopts the following Articles of Incorporation:

ARTICLE I.
NAME

The name of the corporation (which is hereinafter called the "Corporation") shall be AAC Holdings, Inc.

ARTICLE II.
REGISTERED AGENT

The address of the registered office of the Corporation in the State of Nevada is 4625 West Nevso Drive, Suite 2, Las Vegas, Nevada 89103. The name of its registered agent at such address is Registered Agent Solutions, Inc.

ARTICLE III.
CAPITAL STOCK

Section 1. AUTHORIZED SHARES. The aggregate number of shares which the Corporation shall have authority to issue is 75,000,000 shares consisting of 70,000,000 shares of common stock, par value $0.001 per share and 5,000,000 shares of preferred stock, par value $0.001 per share.

Section 2. ISSUANCE AND RIGHTS OF PREFERRED SHARES. The shares of preferred stock may be issued and reissued from time to time in one or more series. The Board of Directors of the Corporation (the "Board") is hereby authorized to fix or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price or prices, the liquidation preference, and any other rights, preferences, privileges, attributes or other matters which may be reserved to the Board by law, of any wholly-unissued series of preferred stock, and the number of shares constituting any such series and the designation thereof; and to increase the number of shares of any series at any time. In case the outstanding shares of any series shall be reacquired or shall not be issued, such shares may be designated or redesignated and altered, and issued or reissued, hereunder, by action of the Board.

Section 3. CUMULATIVE VOTING FOR DIRECTORS. No stockholder of the Corporation shall be entitled to cumulative voting of his or her shares for election of director.

Section 4. PREEMPTIVE RIGHTS. No stockholder of the Corporation shall have any preemptive rights.

ARTICLE IV.
DIRECTORS

Section 1. DIRECTORS. The business and affairs of the Corporation shall be managed under the direction of the Board. The number of directors may be changed from time to time in such manner as shall be provided in the Bylaws of the Corporation. The initial directors are:

Michael T. Cartwright, 115 East Park Drive, Second Floor, Brentwood, TN 37027
Jerrod N. Menz, 115 East Park Drive, Second Floor, Brentwood, TN 37027
Lucius E. Burch, III, 115 East Park Drive, Second Floor, Brentwood, TN 37027
David C. Kloeppel, 115 East Park Drive, Second Floor, Brentwood, TN 37027
Richard E. Ragsdale, 115 East Park Drive, Second Floor, Brentwood, TN 37027
Darrell S. Freeman, Sr., 115 East Park Drive, Second Floor, Brentwood, TN 37027
Jerry Bostelman, 115 East Park Drive, Second Floor, Brentwood, TN 37027

Section 2. LIMITATION OF LIABILITY. The liability of directors and officers of the Corporation shall be eliminated or limited to the fullest extent permitted by the Nevada Revised Statutes. If the Nevada Revised Statutes are amended to further eliminate or limit or authorize corporate action to further eliminate or limit the liability of directors or officers, the liability of directors and officers of the Corporation shall be eliminated or limited to the fullest extent permitted by the Nevada Revised Statutes, as so amended from time to time.

Section 3. REPEAL AND CONFLICTS. Any repeal or modification of Section 2 above approved by the stockholders of the Corporation shall be prospective only, and shall not adversely affect any limitation on the liability of a director or officer of the Corporation existing as of the time of such repeal or modification. In the event of conflict between Section 2 above and any other Article of the Articles of Incorporation, the terms and provisions of Section 2 above shall control.

ARTICLE V.
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Nevada Revised Statutes.

ARTICLE IX.
ARTICLES

Subject to Section 78.390 of the Nevada Revised Statutes, the Corporation reserves the right to repeal, alter, amend or rescind any provision contained in these Articles of Incorporation, in the manner now or hereinafter prescribed by statute, and all rights conferred on stockholders herein are granted subject to this reservation.

IN WITNESS WHEREOF, these Articles of Incorporation has been executed on behalf of AAC Holdings, Inc. by the undersigned officer, thereunto duly authorized, this 12th day of February, 2014.

AAC HOLDINGS, INC.

By: Kathryn S Phillips
Name: Kathryn Sevier Phillips
Title: General Counsel and Secretary

12803497.1

STATE OF NEVADA

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary
for Commercial Recordings



Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701-4201
Telephone (775) 684-5708
Fax (775) 684-7138

OFFICE OF THE
SECRETARY OF STATE

Certified Copy

June 14, 2017

Job Number: C20170614-1753
Reference Number: 00010664678-68
Expedite:
Through Date:

The undersigned filing officer hereby certifies that the attached copies are true and exact copies of all requested statements and related subsequent documentation filed with the Secretary of State's Office, Commercial Recordings Division listed on the attached report.

Document Number(s)	Description	Number of Pages
20140104480-14	Articles of Incorporation	5 Pages/1 Copies



Respectfully,
Barbara K. Cegavske
Barbara K. Cegavske
Secretary of State

Certified By: Jennifer Wilton
Certificate Number: C20170614-1753
You may verify this certificate
online at **http://www.nvsos.gov/**

October 23, 2020

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

Re: **Change of Indirect Ownership – Pharmacy License**

To Whom it May Concern:

Enclosed is the application for change of ownership for the pharmacy license held by the Desert Hope Center, located at 2465 E. Twain Ave, Las Vegas, NV 89121. The license number is IA02919.

The transaction is scheduled to close on November 6, 2020. Due to the structure of the transaction, I have enclosed a transaction summary and ownership chart to help illustrate the level of change that is occurring. Once you have reviewed, we are happy to work with you to provide any additional information that you may need.

Please let me know if you have any questions.

Sincerely,
Tess Meyer
meyert@gtlaw.com
(202) 533-2319

9F

RECEIVED
7-23-2020

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH_____
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☑ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: The Medicine Shoppe Retail Pharmacy

Physical Address: 5801 Craig Dr., Ste. 110

City: Las Vegas, NV State: Zip Code: 89130 Telephone: (725) 251-2646

Fax: (725) 251-2253 Toll Free Number: N/A

E-mail: 2168@medicineshoppe.com

Website: www.medicineshoppe.com

Managing Pharmacist: Jed Lester Anisco License Number: 19983

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding
	For the application to be complete	☐	☑ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Mariana A. T

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mariana Tadros

Print Name of Authorized Person

7/17/2020

Date

Board Use Only	Date Processed:	Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: N/A

Mailing Address: 11027 Sardinia Sands Dr.

City: Las Vegas State: NV Zip: 89141

Telephone: (725) 251-2646 Fax: (725) 251-2253

Contact Person: Mariana Tadros

For any corporation non publicly traded; disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Mariana Tadros - [redacted] Spyglass Dr., Corona, CA 92883
Name Business Address

b) Wael Anwar - [redacted] Lion St., Rancho Cucamonga, CA 91730
Name Business Address

c) Chad Valencia - [redacted] Sardina, Las Vegas NV 89141
Name Business Address

d) N/A
Name Business Address

2) Provide the number of shares issued by the corporation. 5,000

3) What was the price paid per share? $0.00

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 09:00 am 06:00 pm Saturday N/A am N/A pm

Sunday N/A am N/A pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20191561762

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Mariana Tadros

Responsible Person of The Medicine Shoppe Retail Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Mariana A. T

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mariana Tadros
Print Name of Authorized Person

7/17/2020
Date

ACKNOWLEDGMENT

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

State of California
County of Riverside)

On July 17, 2020 before me, D. Antonio Martin Notary Public
(insert name and title of the officer)

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

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

WITNESS my hand and official seal.

D. ANTONIO MARTIN
Comm. #2239451
Notary Public · California
Riverside County
Comm. Expires Jan 26, 2022

Signature D. Antonio Martin (Seal)

Managing Pharmacist

Pharmacist Name: Jed Lester Anisco License #: 19983

Pharmacy Name: The Medicine Shoppe Retail Pharmacy

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Janisco — 7/14/2020

Signature _____ Date _____

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **UNITED HEALTH CARE SOLUTIONS, INC.**, as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 08/27/2019, and is in good standing in this state.

I further certify that the above DOMESTIC CORPORATION (78) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/29/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200629891245
You may verify this certificate online at http://www.nvsos.gov

List of officers and directors

President Mariana Tadros

Secretary Mariana Tadros

Treasurer Mariana Tadros

Director Mariana Tadros

2105

STOCK TRANSFER LEDGER

NAME OF STOCKHOLDER	PLACE OF RESIDENCE	TIME BECAME OWNER	CERTIFICATES ISSUED		FROM WHOM SHARES WERE TRANSFERRED (If Original Issue Enter As Such)	AMOUNT PAID THEREON	DATE OF TRANSFER OF SHARES	TO WHOM SHARES ARE TRANSFERRED	CERTIFICATES SURRENDERED	
			CERTIF. NOS.	NO. SHARES					CERTIF. NOS.	NO. SHARES
Mariana Tadros	[redacted] Spyglass Dr. Corona, CA 92883	9/6/19	1	2000	Original					
Wael Anwar	[redacted] Lion Street Rancho Cucamonga CA 91730	9/6/19	2	2000	Original					
Arturo I. Valencia	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	9/6/19	3	1000	Original		07/15/20	Chad Valencia	3	1000
Chad Valencia	[redacted] Sardinia Sands Dr. Las Vegas, NV 89141	07/15/20	4	1000	Arturo Valencia	$1.00				

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

2106

Date 7/17/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

The Medicine Shoppe Retail Pharmacy - 5801 Craig Dr., ~~Unit B~~ Ste. 110, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Tadros — Last Name
Mariana — First Name
Awni Al Fakhouri — Middle Name

Maiden name: "Mariana Alfakhouri"
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Spyglass Dr., Corona, CA 92833
Present Residence Address-Street or RFD — City — State/Zip

9194 Magnolia Ave., Riverside, CA 92503 Dates 04/2015 - Present
Present Business Address — City — State/Zip

Administration/Manager Dates 04/2018 - Present
Occupation

Phone: Residence [redacted]
Business (951) 977-8667

[redacted]
Date of Birth

Al Salt , Amman, Jordan
Place of Birth (City, County, State)

33 — Age
[redacted] — Social Security Number
Female — Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Light	119lbs	Slim	5'4"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No [redacted] Date 10/14/2015

Place Los Angeles, CA (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☑ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial MT

A. **Current Marriage** 11/10/2013 (Date) Pasadena, Los Angeles, CA (City, County and State)

Spouse's full name (Maiden) Michael Tadros S.S. No [redacted]

Date of Birth [redacted] Place of Birth Cairo, Egypt

Resident address [redacted] Spyglass Dr., Corona, CA 92833 (Street / City / State / Zip)

Telephone: Residence [redacted] Business (909) 542-9365

Spouse's employer The Medicine Shoppe Occupation Pharmacist / Pharmacy Owner

Address of employer 9675 Monte Vista Ave., Ste. A, Montclair, CA 91763 (Street / City / State / Zip)

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Edward Tadros	[redacted]	Newport Beach, CA	[redacted] Spyglass Dr., Corona, CA 92833
Ethan Tadros		Newport Beach, CA	[redacted] Spyglass Dr., Corona, CA 92833
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial M.T

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Awni Alfakhouri Father	[redacted]	[redacted] Spyglass Dr., Corona, CA 92833	Clerk
Raghda Alfakhouri Mother		[redacted] Spyglass Dr., Corona, CA 92833	Home maker
Edward Tadros (deceased) Father-in-Law		Cairo Egypt	Teacher
Nariman Hanna Mother-In-Law		[redacted] Spyglass Dr., Corona, CA 92833	Teacher

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Hisham Alfakhouri	[redacted]	Alsalt, Jordan	Sales Representative
Spouse Rita Dawoud		Alsalt, Jordan	Medical Assistant
Hussam Alfakhouri		Alsalt, Jordan	Sales Representative
Spouse Mera Fakhoury		Alsalt, Jordan	Preschool Principle
N/A			
Spouse N/A			
N/A			
Spouse N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	N/A	N/A	N/A	Yes ☐ No ☐
High School	Granite Hills	Apple Valley, CA	2002 - 2004	Yes ☑ No ☐
College University	La Sierra University	Riverside, CA	2007 - 2010	Yes ☑ No ☐
Other				Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science - Biology

College or university where obtained La Sierra University

Applicant's initial M.T

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☑
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial M.T

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
04/2015 - Present	[redacted] Spyglass Dr., Corona, CA 92883		
09/2013 - 03/2015	2494 Dakin Dr., Corona, CA 92882		
04/2008 - 09/2013	7024 Miami St., Riverside, CA 92506		
05/2002 - 04/2008	16421 Apple Valley Rd,. #4, Apply Valley, CA 92307		
07/1995 - 05/2002	Alsalt, Jordan		
N/A			
N/A			
N/A			
N/A			
N/A			

Applicant's initial M.T

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

04/2018 - Present	The Medicine Shoppe - 9194 Magnolia Ave., Riverside, CA 92503	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
CEO	Administration and Management	Self
Title	Description of Duties	Name of Supervisor
06/2015 - 04/2018	The Medicine Shoppe - 10237 Magnolia Ave., Riverside, CA 92503	Business Closure
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Human Resources Associate	Assist with employee training, relations, benefits, compensation	Michael Tadros
Title	Description of Duties	Name of Supervisor
12/2013 -	Allergan - 2525 Dupont Dr, Irvine, CA 92612	Laid off
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Compounding Management Associate	Compound inventory, preparation, and data entry	Nady Mettais
Title	Description of Duties	Name of Supervisor
07/2013 - 12/2013	Adecco Medical Sciences - 2525 Dupont Dr, Irvine, CA 92612	Hired at Allergan
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Compounding Management Associate	Compound inventory, preparation, and data entry	Nady Mettias
Title	Description of Duties	Name of Supervisor
09/2010 - 08/2012	LLVare - 710 Brookside Ave, Redlands, CA 92373	Personal Reasons
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Research Technician	Isolation of RNA & DNA, measurements of mRNA & pre-mRNA	Yossouf Amaar
Title	Description of Duties	Name of Supervisor
01/2009 - 06/2010	La Sierra University - 4500 Riverwalk Pkwy, Riverside, CA 92505	Contract Ended
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Teacher Assistant	Assistance in office & lab classes for Physics & Biology	Eugene Joseph
Title	Description of Duties	Name of Supervisor
10/2004 - 01/2009	N/A	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Unemployed		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial M.T

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Rindala Obeid	Home Loma Linda, CA 92354				[redacted]	12
Employer Kaiser	Business 9961 Sierra Ave, Fontana, CA 92335				(833) 574-2273	
Name Miriam Nagoulat	Home San Bernardino, CA 92346				[redacted]	13
Employer Loma Linda University	Business 25455 Barton Rd., Loma Linda, CA 92354				(909) 558-4000	
Name Uyan Azia	Home Eastvale, CA 92880				[redacted]	11
Employer Riverside University Health System	Business 4065 County Circle Dr., Riverside, CA 92503				(951) 358-5000	
Name Dina Wasef	Home Corona, CA 92882				[redacted]	11
Employer Kaiser	Business 10800 Magnolia Ave, Riverside, CA 92505				(833) 574-2273	
Name Hamsa Azar	Home Upland, CA 91784				[redacted]	10
Employer Kaiser	Business Sierra Ave, Fontana, CA 92335				(833) 574-2273	

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☑ No ☐
If yes, state type, where and years held
Liquor - Irvine, CA - 2019
N/A
N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☑ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

(Pharmacy; 04/2018 - Present; The Medicine Shoppe; 9194 Magnolia Ave., Riverside, CA 92503; California State Board of Pharmacy)
(Pharmacy; 02/2019 - Present; The Medicine Shoppe; 31946 Mission Trl., Ste. A-1, Lake Elsinore, CA 92530; California State Board of Pharmacy
Partner - Fady Mosaad - 3100 Van Buren Blvd., #924, Riverside, CA 92503)
(Restaurant; 11/2014 - Present ; Cafe 350 - 350 Commerce, Unit 150, Irvine, CA 92602
Partner - Gerges 704 Pointe Vista Ln., Corona, CA 92881)

Applicant's initial M.T

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☑ No ☐



Date of photograph 7/2/2020

Applicant's initial MT

STATE OF California

ss.

COUNTY OF Riverside

I, Mariana Tadros, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Mariana A. T

Original Signature of Applicant

Subscribed and Sworn to before me this 17 day of July 2020

D. Antonio Mtn

Notary Public

(seal)

D. ANTONIO MARTIN
Comm. #2239451
Notary Public · California
Riverside County
Comm. Expires Jan 26, 2022

Applicant's initial M.T

ADDITIONAL INFORMATION

N/A

Applicant's initial M.T

THE UNITED STATES OF AMERICA

No. [redacted]

CERTIFICATE OF NATURALIZATION

USCIS Registration No. A095[illegible]

Personal description of holder at time of naturalization:

Date of birth: [redacted]

Sex: FEMALE

Height: 5 feet 4 inches

Current marital status: MARRIED

Country of former nationality: JORDAN



I certify that the description given on this certificate is true and that the photograph affixed hereto is a likeness of me.

[redacted]

Having made a petition for naturalization to the United States

at SAN BERNARDINO, CALIFORNIA

[redacted]

MARIANA ABDELRAHEEM ZAHROUT ZAHROS

at CORONA, CALIFORNIA

was admitted to citizenship at a naturalization ceremony conducted by the

US DISTRICT COURT CENTRAL DISTRICT

at LOS ANGELES, CALIFORNIA on OCTOBER 6, 2015

[redacted]

DEPARTMENT OF HOMELAND SECURITY

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 07/16/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

The Medicine Shoppe Retail Pharmacy - 5801 Craig Dr., ~~Unit B~~ Ste. 110, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name	First Name	Middle Name
Anwar	Wael	Nabil

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Lion St., Rancho Cucamonga, CA 91730
Present Residence Address-Street or RFD — City — State/Zip

1 World Way, Los Angeles, CA 90045 Dates 09/2012 - Present
Present Business Address — City — State/Zip

Flight Attendant Dates 06/2001 - Present
Occupation

Phone: Residence [redacted]
Business (800) 693-3582

[redacted] Cairo, Egypt
Date of Birth — Place of Birth (City, County, State)

43 [redacted] Male
Age — Social Security Number — Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Light	185lbs		5'7"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No [redacted] Date 07/22/2005

Place Pomona, CA (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☑ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial WA

A. **Current Marriage** 05/21/2006 (Date) Mississauga, ON, Canada (City, County and State)

Spouse's full name (Maiden) Maria F. Kozman S.S. No [redacted]

Date of Birth [redacted] Place of Birth Cairo, Egypt

Resident address [redacted] Lion St., Rancho Cucamonga, CA 91730
Street City State Zip

Telephone: Residence [redacted] Business N/A

Spouse's employer Self Occupation Homemaker

Address of employer 7481 Lion St., Rancho Cucamonga, CA 91730
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Paul Anwar	[redacted]	Glendora, CA	[redacted] Lion St., Rancho Cucamonga, CA 91730
Mina Anwar		Glendora, CA	[redacted] Lion St., Rancho Cucamonga, CA 91730
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial WA

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

Name (Maiden)	Birth Date	Address	Occupation
Nabil Awad Father	[redacted]	[redacted] Archiblad Ave., Rancho Cucamonga, CA 91701	Manager
Zeizaf Ibrahim Mother		[redacted] Archiblad Ave., Rancho Cucamonga, CA 91701	Home Maker
Fayez Mousa Kozman Father-in-Law		[redacted] Mohamad Abdalla St., Cairo, Egypt	Public Relations Manager
Kamilia Abdelsayed Mother-in-Law		[redacted] Lion St., Rancho Cucamonga, CA 91730	Home Maker

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Sameh Awad Spouse	[redacted]	[redacted] Elder Eastwood Ave., Orange, CA 92689	Business Owner
Maria Botrous		[redacted] Elder Eastwood Ave., Orange, CA 92689	Home Maker
N/A Spouse			
N/A			
N/A Spouse			
N/A			
N/A Spouse			
N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	College Patriarcal	Egypt	1981-1990	Yes ☑ No ☐
High School	College De La Salle	Egypt	1990 - 1993	Yes ☑ No ☐
College University	Helwan University	Egypt	1994 - 1998	Yes ☑ No ☐
Other	N/A			Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science - Commerence & Business Administration

College or university where obtained Helwan University

Applicant's initial WA

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☑
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial WA

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
09/2012 - Present	[redacted] Lion St.,	Rancho Cucamonga,	CA 91730
01/2007 - 08/2012	8837 Grove Ave., #1403,	Rancho Cucamonga,	CA 91730
02/2005 - 12/2006	8722 Lomita Dr., #B,	Alta Loma,	CA 91701
02/2003 - 01/2005	10040 Placer St., #D,	Rancho Cucamonga,	CA 91730
06/2002 - 01/2003	271 Brevoort St.,	Kew Gardens,	NY 11415
01/2002 - 05/2002	83-33 118th St.,	Kew Gardens,	NY 11415
04/2001 - 12/2001	83-09 Talbot St., #PH-6E,	Kew Gardens,	NY 11415
01/2001 - 03/2001	9427 Cameron Ave.,	Rancho Cucamonga,	CA 91729
01/2000 - 12/2000	3730 Pacific Ave.,	Riverside,	CA 92509
10/1999 - 12/1999	1010 W. Badillo St.,	West Covina,	CA 91790
12/1994 - 09/1999	13 Kaitbay St.,	Heliopolis, Cairo,	Egypt

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

06/2001 - Present	Delta Airlines - 1 World Way, Los Angeles, CA 90045	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Flight Attendant	Guide and assist the safety and comfort of passengers	Jesse Rhodes
Title	Description of Duties	Name of Supervisor
12/2010 - Present	Miracle Medical Industries, Inc. - 1701 S. Vineyard Ave., #E, Ontario, CA 91761	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
CEO	Importing and Distribution of Medical Supplies	Self
Title	Description of Duties	Name of Supervisor
09/2013 - 12/2014	Delicare Medical Supplies - 2132 S. Grove Ave., #6, Ontario, CA 91761	Closure of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President	Distribution of Medical Supplies	Self
Title	Description of Duties	Name of Supervisor
03/2005 - 12/2010	Valero - 01 W. 6th St., Corona, CA 92882	Sale of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President/Officer	Manage, own, and operate gas station	Self
Title	Description of Duties	Name of Supervisor
01/2003 - 02/2005	Valaro - 5700 Atlantic Blvd., Maywood, CA 90270	Sale of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President/Officer	Manage, own, and operate gas station	Self
Title	Description of Duties	Name of Supervisor
01/2000 - 05/2001	Mobil - 6824 Valley Way, Riverside, CA 92509	Hired at Delta Airlines
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Manager	Managing employees and daily operations	Nagy Attalla
Title	Description of Duties	Name of Supervisor
06-1999 - 09/1999	Delta Bank - 1191 Komich El Nile , Downtown , Cairo , Egypt.	Immigrated to USA
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Accountant	Process letter of credits to receive and send internationally	Tarek
Title	Description of Duties	Name of Supervisor
08/1998 - 05-1999	N/A	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Unemployed		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial WA

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Adel Ebeid	Home [redacted] Church St., Apt 106, Rancho Cucamonga CA 91730				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Ramy Barsoum	Home [redacted] Shelby P., Apt 136 Rancho Cucamonga, CA 91739				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Philip Youssef	Home [redacted] Melbourne Pl., Riverside CA 92508				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Marianna Tadros	Home [redacted] Spyglass Dr., Corona, CA 92883				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Michael Tadros	Home [redacted] Spyglass Dr., Corona, CA 92883				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑
If yes, state type, where and years held
N/A
N/A
N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.
N/A
N/A
N/A

Applicant's initial WA

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑



Date of photograph 06/20/20

Applicant's initial WA

STATE OF California ss.

COUNTY OF San Bernardino

I, WAEL N. ANWAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

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

.....

.....
Notary Public

(seal)

See Attached
Notarial Certificate

Applicant's initial WA

CALIFORNIA JURAT

(CALIFORNIA GOVERNMENT CODE § 8202)

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

STATE OF CALIFORNIA
COUNTY OF San Bernardino

Subscribed and sworn to (or affirmed) before me on this 16 day of July, 2020,
by Wael Nabil Anwar, proved to me on the basis of
(Name of Signer(s))
satisfactory evidence to be the person(s) who appeared before me.

CONTESSA RENEA LEE
Notary Public - California
San Bernardino County
Commission # 2180146
My Comm. Expires Jan 16, 2021

Signature of Notary Public (Notary Seal)

ADDITIONAL OPTIONAL INFORMATION

Description of Attached Document

Title or Type of Document: Personal History Document Date: 7/16/2020

Number of Pages: 10 Signer(s) Other Than Named Above: N/A

Additional Information: N/A

ADDITIONAL INFORMATION

N/A

Applicant's initial WA

THE UNITED STATES OF AMERICA

No. [redacted]

CERTIFICATE OF NATURALIZATION

Personal description of holder as of date of naturalization:

Date of birth: [redacted]

Sex: **MALE**

Height: **5** *feet* **7** *inches*

Marital status: **SINGLE**

Country of former nationality:
EGYPT



CIS Registration No.: **A046835842**

I certify that the description given is true, and that the photograph affixed hereto is a likeness of me.

(Complete and true signature of holder)

Be it known that, pursuant to an application filed with the Secretary of Homeland Security

at: **LOS ANGELES, CALIFORNIA**

The Secretary having found that:

WAEL NABIL ANWAR

then residing in the United States, intends to reside in the United States when so required by the Naturalization Laws of the United States, and had in all other respects complied with the applicable provisions of such naturalization laws and was entitled to be admitted to citizenship, such person having taken the oath of allegiance in a ceremony conducted by the

US DISTRICT COURT CENTRAL DISTRICT

at: **POMONA, CALIFORNIA** *on:* **JULY 22, 2005**

that such person is admitted as a citizen of the United States of America.

Director, U. S. Citizenship and Immigration Services

IT IS PUNISHABLE BY U. S. LAW TO COPY, PRINT OR PHOTOGRAPH THIS CERTIFICATE, WITHOUT LAWFUL AUTHORITY.

DEPARTMENT OF HOMELAND SECURITY

FORM N-550 REV. 4-04

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 07-16-2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy STE. 110
Nature of License

The Medicine Shoppe Retail Pharmacy - 5801 Craig Dr., ~~Unit B~~, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name	First Name	Middle Name
Valencia	Chad	Alexander

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Sardinia Sands Dr., Las Vegas, NV 89141
Present Residence Address-Street or RFD — City — State/Zip

6432 Beckman Glen Ct., Las Vegas, NV 89141 Dates 10/2019 - Present
Present Business Address — City — State/Zip

Data Analyst/Scientist, Consultant Dates 10/2019 - Present
Occupation

Phone: Residence [redacted]
Business (626) 672-6902

[redacted] CV
Date of Birth

Whitter, Los Angeles, CA
Place of Birth (City, County, State)

37 [redacted] Male
Age — Social Security Number — Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Tan	220lbs	Large	5'7"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☑ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial

MARITAL INFORMATION-Continued

A. **Current Marriage**.....
Date City, County and State

Spouse's full name (Maiden)..... S.S. No.....

Date of Birth..... Place of Birth.....

Resident address.....
Street City State Zip

Telephone: Residence ..... Business .....

Spouse's employer..... Occupation.....

Address of employer.....
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
N/A			
N/A			
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial CW

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Arturo Valencia	[redacted]	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	Business Development
Mother	Cristina Enrile		Sardinia Sands Dr., Las Vegas, NV 89141	Accountant
Father-in-Law	N/A			
Mother-in-Law	N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Robert Valencia	[redacted]	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	Teacher
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	GSE / Suzanne Middle School	Walnut, CA	09/1991 - 06/1996	Yes ☑ No ☐
High School	Walnut High School	Walnut, CA	09/1997 - 06/2000	Yes ☑ No ☐
College University	UCLA	Los Angeles, CA	09/2000 - 06/2003	Yes ☑ No ☐
Other				Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science, Mathematics-Economics

College or university where obtained University of California, Los Angeles

Applicant's initial

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☑ No ☐
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
Art Valencia	Father	Immigration Fraud	Los Angeles, CA	2008
N/A				
N/A				

Applicant's initial

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
10/2019 - Present	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141		
09/2018 - 10/2019	39-20 52nd St., Apr. 3F, Woodside, NY 11377		
03/2013 - 09/2018	4657 Laurel Ridge Dr., Riverside, CA 92509		
09/2012 - 03/2013	11027 Sardinia Sands Dr., Las Vegas, NV 89141		
09/2009 - 09/2012	6432 Beckman Glen Ct., Las Vegas, NV 89141		
01/2007 - 09/2009	4657 Laurel Ridge Dr., Riverside, CA 92509		
09/2005 - 01/2007	39-20 52nd St., Apr. 3F, Woodside, NY 11377		
06/2003 - 09/2005	304 Muirfield Ln., Walnut, CA 91789		
06/2002 - 06/2003	535 Gayley Ave., Los Angeles, CA 90024		
09/2000 - 06/2002	350 De Neve Dr., Los Angeles, CA 90024		
12/1994 - 09/2000	304 Muirfield Ln., Walnut, CA 91789		

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

05/2019 - 12/2019	Noble Desktop - 185 Madison Ave., New York, NY 10016	Moved to Las Vegas
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Instructor	Taught data science courses	Zach Cohen
Title	Description of Duties	Name of Supervisor
05/2018 - 05/2019	Codecademy - 575 Broadway, New York, NY 10012	Moved to New York
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Instructor	Taught data science courses	Tracy Teague
Title	Description of Duties	Name of Supervisor
10/2017 - Present	Freelance Data Scientist	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Data Scientist	Independent Data Projects	Self
Title	Description of Duties	Name of Supervisor
10/2004 - 09/2017	Owl Homecare Pharmacy - 13851 Garvey Ave Suite A Baldwin Park, CA 91706	Business Closure
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Analyst	Billing Analysis and Consulting	Cristina Valencia
Title	Description of Duties	Name of Supervisor
10/2001 - 10/2004	Unemployed	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A	N/A	N/A
Title	Description of Duties	Name of Supervisor
10/2000 - 10/2001	UCLA Access Control - 330 De Neve Dr, Los Angeles, California 90024	Focus on graduating
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Volunteer	Access Monitor Security for Droms	Junji Toshima
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial .....

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Jane Lagunilla	Home [redacted] White Sands Way, Arverne, NY 11692				[redacted]	15
Employer Memorial Sloan Kettering	Business 16 E. 60th St., New York, NY 10022				(646) 888-6001	
Name Theresa Francisco	Home [redacted] White Sands Way, Arverne, NY 11692				[redacted]	30
Employer Retired	Business N/A					
Name Tony Chou	Home [redacted] Walnut Canyon Rd., Walnut, CA 91789				[redacted]	25
Employer LA-USC	Business 2051 Marengo St., Los Angeles, CA 90033				(323) 409-1000	
Name David Aure	Home [redacted] Scotch Pine Ridge, Yorba Linda, CA 92886				[redacted]	25
Employer Realtor	Business 5685 Scotch Pine Ridge, Yorba Linda, CA 92886				(714) 944-2933	
Name Brandon Nichols	Home [redacted] Overland St., Riverside, CA 92503				[redacted]	10
Employer Self-Employed	Business 3822 Overland St., Riverside, CA 92503				(951) 999-0339	

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑
If yes, state type, where and years held
N/A

N/A

N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.
N/A

N/A

N/A

Applicant's initial CV

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑

ATTACH PHOTOGRAPH



Date of photograph 07-16-2020

Applicant's initial

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

STATE OF Nevada

ss.

COUNTY OF Clark

I, CHAD VALENCIA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent, and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 16th day of July 2020

Notary Public

(seal)

STEFANIE PARLADE
Notary Public - State of Nevada
County of Clark
APPT. NO. 18-3090-1
My App. Expires July 12, 2022

Applicant's initial

ADDITIONAL INFORMATION

N/A

Applicant's initial

GEORGE S. CARDONA
United States Attorney
THOMAS P. O'BRIEN
Assistant United States Attorney
Chief, Criminal Division
ELISA FERNANDEZ (Cal. State Bar No. 172004)
Assistant United States Attorney
Public Corruption & Civil Rights Section
1300 United States Courthouse
312 North Spring Street
Los Angeles, California 90012
Telephone: (213) 894-7383
Facsimile: (213) 894-6436
E-mail: Elisa.fernandez@usdoj.gov

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ARTURO VALENCIA, Defendant.	CR No. 05-0002-PA STIPULATION TO CONTINUE DEFENDANT ARTURO VALENCIA'S SENTENCING HEARING Sentencing Date: July 20, 2007 Proposed Date: January 7, 2008

Plaintiff United States of America, by and through its counsel of record, the United States Attorney for the Central District of California, defendant Arturo Valencia ("Valencia"), individually and through his counsel, Federal Public Defender Nadine Hettle, hereby agree and jointly stipulate, and request that the court continue defendant Valencia's sentencing hearing from July 20, 2007, at 8:30 a.m., to January 8, 2008, at 8:30

///

///

a.m. for the following reasons:

1. On February 14, 2005, defendant Valencia pled guilty to a two-count information of conspiring to commit immigration fraud and his participation in an immigration fraud scheme which involved the law corporation of Korenberg, Abramowitz & Feldun ("KAF").

2. After defendant entered his guilty plea, the government continued its investigation into the illegal activities of KAF in relation to KAF's partners, associates and employees who participated in an immigration fraud scheme. To that end, defendant agreed to assist the government in completing its investigation, and has been doing so since entering his guilty plea.

3. Two partners of the KAF law firm, Daniel Korenberg ("Korenberg") & Steven Rodriguez ("Rodriguez"), have been indicted on presenting false immigration documents and petitions to the Immigration and Naturalization Service ("INS") in violation of Title 18, United States Code, Sections 371, 1001, and 1546(a). Korenberg and Rodriguez are set to proceed to trial on October 16, 2007.

4. Several defendants are scheduled to be sentenced in November and December 2007. Defendant Valencia's cooperation may be needed to prepare for those sentencings.

5. Defendant presently is on bond and has fully complied with all of the terms of pretrial release. Neither defendant nor defendant's counsel object to a continuance of the sentencing in this matter. Therefore, the parties request that defendant's sentencing date be continued to December 3, 2007 to provide

defendant further opportunity to cooperate and for the government to evaluate the scope and extent of defendant's cooperation and file a Section 5K1.1 motion, if warranted. The parties also request a continuance in the time to respond to the Presentence Report, and agree to serve the Probation Department their respective response by hand delivery.

Accordingly, the parties jointly request that the sentencing in this matter should be continued from July 20, 2007 to January 8, 2008, at 8:30 a.m.

June ___, 2007

Respectfully submitted

GEORGE S. CARDONA
United States Attorney

ELISA FERNANDEZ
Assistant United States Attorney

Attorneys for Plaintiff
United States of America

June ___, 2007

ARTURO VALENCIA
Defendant

June ___, 2007

NADINE HETTLE
Attorney for Defendant
ARTURO VALENCIA

GEORGE S. CARDONA
United States Attorney
THOMAS P. O'BRIEN
Assistant United States Attorney
Chief, Criminal Division
ELISA FERNANDEZ (Cal. State Bar No. 172004)
Assistant United States Attorney
Public Corruption & Civil Rights Section
1300 United States Courthouse
312 North Spring Street
Los Angeles, California 90012
Telephone: (213) 894-7383
Facsimile: (213) 894-6436

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ARTURO VALENCIA, Defendant.	CR No. 05-0002-PA [PROPOSED] ORDER REGARDING STIPULATION TO CONTINUANCE SENTENCING HEARING FOR DEFENDANT ARTURO VALENCIA Sentencing Date: July 20, 2007 Proposed Date: January 7, 2008

GOOD CAUSE HAVING BEEN SHOWN in the parties stipulation to continue the sentencing in the above-entitled matter from July 20, 2007 to January 7, 2008, at 8:30 a.m., IT IS FOUND AND ORDERED that the sentencing in this matter is continued from July 20, 2007 to January 7, 2008, at 8:30 a.m. IT IS FURTHER ORDERED THAT Defendant Arturo Valencia appear on January 8, 2008,

///

///

///

at 8:30 a.m. in the courtroom of the Honorable Percy Anderson located at 312 N. Spring Street, Los Angeles, California, Courtroom 15.

DATED: June __, 2007

THE HON. PERCY ANDERSON
United States District Judge

Submitted By:

ELISA FERNANDEZ

defendant further opportunity to cooperate and for the government to evaluate the scope and extent of defendant's cooperation and file a Section 5K1.1 motion, if warranted. The parties also request a continuance in the time to respond to the Presentence Report, and agree to serve the Probation Department their respective response by hand delivery.

Accordingly, the parties jointly request that the sentencing in this matter should be continued from July 20, 2007 to January 8, 2008, at 8:30 a.m.

June ___, 2007

Respectfully submitted

GEORGE S. CARDONA
United States Attorney

ELISA FERNANDEZ
Assistant United States Attorney

Attorneys for Plaintiff
United States of America

June ___, 2007

ARTURO VALENCIA
Defendant

June ___, 2007

NADINE HETTLE
Attorney for Defendant
ARTURO VALENCIA

FEDERAL PUBLIC DEFENDER
321 East 2nd Street
Los Angeles, California 90012-4202

Telephone (213) 894-2854
Facsimile (213) 894-0081

FACSIMILE TRANSMISSION COVER SHEET

Date Sent:

TO:

NAME: Arturo Valencia

FAX #: 951-727-0696 **VOICE #:**

Number of Pages to Follow: 5

FROM: Nadine Hettle

COMMENTS: Art, just return the signature page (p. 3)

IN EVENT OF TRANSMISSION ERROR OR FOR VOICE COMMUNICATION

FAX (213) 894-0081 or CALL (213) 894-2854

THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL NAMED ABOVE. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE. THANK YOU.

2 attorneys charged with work visa fraud

The immigration lawyers allegedly filed false applications for foreign nationals employed at their firm, and perhaps for others.

By Anna Gorman
Times Staff Writer

Two local immigration attorneys have been charged with fraud after allegedly filing false employment visa applications for 14 foreign nationals working for their firm, according to a federal grand jury indictment released Thursday.

The lawyers, of ASK Law Group in Sherman Oaks, filed the fraudulent applications and paid their employees in cash while awaiting approval for the visas, according to the indictment. Investigators believe the attorneys also filed false visa applications on behalf of hundreds of other foreigners looking for work at other companies.

"This is the largest immigration fraud probe ever mounted against a Los Angeles-area law firm," said Jennifer Silliman, deputy special agent in charge of the local office of Immigration and Customs Enforcement.

The indictment charges Daniel Korenberg, a senior partner at the law firm, and Steven James Rodriguez, a senior associate, with visa fraud and conspiracy to commit visa fraud. Korenberg faces a possible sentence of 225 years in federal prison. Rodriguez faces up to 15 years in prison.

Another partner in the firm, Philip Abramowitz, 53, has already pleaded guilty to conspiracy and visa fraud.

The indictment accused the men of committing fraud between 2000 and 2003.

To obtain an employment visa for a foreign worker, a company must prove it cannot find a qualified U.S. employee to fill a specific job. The H-1B visas are limited to foreign workers with at least a bachelor's degree. Firms must pay foreign workers the prevailing wage.

Investigators said Korenberg, 57, and Rodriguez, 40, wrote false job titles and salaries on the visa applications, citing jobs that didn't exist. They also allegedly lied about the foreigners' work experience.

The fake job titles included accountant, human resources specialist and systems analyst/programmer. The employees were actually doing secretarial work, investigators said.

Several were here on visitors' visas, which did not allow them to work, agents said.

U.S. Citizenship and Immigration Services plans to review all the visa applications that are suspect, said spokeswoman Marie Sebrechts. If applicants were complicit in any fraud, their visas could be revoked, she said.

The ASK Law Group is based in Sherman Oaks, but has offices in Los Angeles, San Diego, San Francisco and Las Vegas. According to the firm's website, lawyers provide services to individuals, small businesses and large corporations.

Because the defendants are attorneys, Silliman said, they know how to work the system and get around loopholes.

"It's always disturbing when attorneys manipulate the system for financial gain," said Thom Mrozek, spokesman for the U.S. attorney's office in Los Angeles.

Korenberg, Abramowitz and Rodriguez did not return calls for comment. Korenberg and Rodriguez are scheduled to appear in U.S. District Court in Los Angeles on March 29.

The firm had a decent reputation, so the charges were shocking, said John Ayala, vice chairman of the Southern California chapter of the American Immigration Lawyers Assn.

"We hope the allegations are not true," Ayala said. "If they are found true, I think it's an aberration. It doesn't reflect the immigration bar of Southern California."

anna.gorman@latimes.com

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date 7/14/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of Pharmacy or Wholesaler

The Medicine Shoppe Retail Pharmacy - 5801 Craig Dr., ~~Unit A~~ STE 110, Las Vegas, NV 89130
Name and Address of Business for Which Designated Representative Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Anisco	Jed Lester	Bartolome
Last Name	First Name	Middle Name

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Kings Dominion Ct., Henderson, NV 89052
Present Residence Address-Street or RFD — City — State/Zip

2011 E. Lake Mead Blvd., North Las Vegas, NV 89030 Dates 07/01/2020 - Present
Present Business Address — City — State/Zip

Pharmacist-In-Charge Dates 07/01/2020 - Present
Present Position with the Pharmacy or Wholesaler

Phone: Residence [redacted]

Business (702) 649-1991

[redacted]
Date of Birth

Mandaluyong City, Philippines
Place of Birth (City, County, State)

26 Age — [redacted] Social Security Number — M Sex

Black	Black	Dark	160lbs	Slim	6'0"
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No.

If naturalized, certificate No [redacted] Date 05/26/2017

Place Las Vegas, NV (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☑ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial JLA

MARITAL INFORMATION-Continued

A. **Current Marriage** N/A

Date: N/A — City, County and State: N/A

Spouse's full name (Maiden) N/A — S.S. No N/A

Date of Birth N/A — Place of Birth N/A

Resident address N/A
Street City State Zip

Telephone: Residence N/A — Business N/A

Spouse's employer N/A — Occupation N/A

Address of employer N/A
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
N/A			
N/A			
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial JLA

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Amador Anisco	[redacted]	[redacted] Kings Dominion Ct., Henderson, NV 89052	Dialysis Patient Care Technician
Mother	Lalaine Bartolome		Kings Dominion Ct., Henderson, NV 89052	Registed Nurse
Father-in-Law	N/A			
Mother-in-Law	N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Jeremie Luis Anisco	[redacted]	[redacted] Kings Dominion Ct., Henderson, NV 89052	Registered Nurse
Spouse	N/A			
	Lian June Anisco		Kings Dominion Ct., Henderson, NV 89052	Student
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Colegio De La Purisima Concepcion	Roxas City, Philippines	2003-2009	Yes ☑ No ☐
High School	Coronado High School	Henderson, NV	2009-2012	Yes ☑ No ☐
College University	Nevada State College	Henderson, NV	2012-2015	Yes ☐ No ☑
Other	Roseman University of Health Sciences	Henderson, NV	2015-2018	Yes ☑ No ☐

Type of degree obtained, if any Doctor of Pharmacy (Pharm D)

College or university where obtained Roseman University of Health Sciences

Applicant's initial VH

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☑ No ☐

County Clark State NV Date registered 01/03/2012

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☑ No ☐
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial JLA

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation, ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
07/2012 - Present	[redacted] Kings Dominion Ct., Henderson, NV 89052		
08/2009 - 07/2012	2305 W. Horizon Ridge Pkwy., Unit 3112, Henderson, NV 89052		
05/2009 - 08/2009	1655 E. Sahara Ave., Apt. 1079, Las Vegas, NV 89104		
05/2003 - 05/2009	Brgy Culasi, Roxas City, Capiz 5800, Philippines		
08/1993 - 05/2003	Unit 138, Bldg 1, Phase 1, Sikatuna Bliss, Diliman, Quezon City, Philippines		
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			

Applicant's initial JLA

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

09/2018 - Present	CVS Pharmacy - 8116 S. Las Vegas Blvd., Las Vegas, NV 89123	4000
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Pharmacist	Final check of prescriptions and perform patient consultations	Lauren Naft / Shanela Blas-Catacutan
Title	Description of Duties	Name of Supervisor
10/2015 – 9/2018	CVS Pharmacy - 2830 Bicentennial Pkwy., Henderson, NV 89052	1500
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Intern Pharmacist	Stock, prepare and verify prescriptions and medications	Marilu Caudal / Kyle Folk
Title	Description of Duties	Name of Supervisor
02/2015 - 10/2015	CVS Pharmacy - 2830 Bicentennial Pkwy., Henderson, NV 89052	600
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Tech-In-Training	Receive prescriptions and verify insurance	Marilu Caudal
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
N/A		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial JLA

Mark I. Sedar

From: Lanz, Luis J. <Luis.Lanz@quarles.com>
Sent: Tuesday, January 26, 2021 5:11 PM
To: Mark I. Sedar
Cc: Morris, Roger N.
Subject: RE: The Medicine Shoppe Pharmacies: Request for Temporary Permit [QBLLP-ACTIVE.FID41317955]

Mark, I just confirmed with Mr. Anisco that the employment dates for CVS Pharmacy – 2830 Bicentennial Pkwy., Henderson, NV are 10/2015 - 09/2018.

Please let me know if you have any additional questions or concerns. Thank you!

Luis

From: Mark I. Sedar <msedar@pharmacy.nv.gov>
Sent: Tuesday, January 26, 2021 5:38 PM
To: Lanz, Luis J. (PHX x3331) <Luis.Lanz@quarles.com>
Cc: Morris, Roger N. (PHX x3269) <Roger.Morris@quarles.com>
Subject: RE: The Medicine Shoppe Pharmacies: Request for Temporary Permit [QBLLP-ACTIVE.FID41317955]

The tech-in-trainee hours are counted, however the dates on the form that are confusing which would result in the hours not being accurate.

Mark Sedar
Chief Operating Officer
Nevada State Board of Pharmacy
(775) 850-1440
msedar@pharmacy.nv.gov

[bing.com]

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Lanz, Luis J. <Luis.Lanz@quarles.com>
Sent: Tuesday, January 26, 2021 4:24 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Marilu Caudal	Home [redacted] Alder Center Dr., Apt. 16108, Henderson, NV 89052				[redacted]	5
Employer CVS	Business 2011 E. Lake Mead Blvd., N. Las Vegas, NV 89030				(702) 649-1991	
Name Glecille Salonga	Home [redacted] Duck Harbor Ave., North Las Vegas, NV 89031				[redacted]	5
Employer Honor Health	Business 10200 N. 92nd, Ste. 140, Scottsdale, AZ 85258				(480) 583-4000	
Name Isabel Ibanez	Home [redacted] Stone Valley Dr., Apt. 4203, Reno, NV 89523				[redacted]	5
Employer VA	Business 975 Kirman Ave., Reno, NV 89502				(844) 698-2311	
Name Aira Joy Canlapan	Home [redacted] Longshot Dr., Las Vegas, NV 89122				[redacted]	5
Employer VA	Business 6900 N. Pecos Rd., North Las Vegas, NV 89086				(702) 791-9000	
Name Christian Sy	Home [redacted] Stone Valley Dr., Apt. 4203, Reno, NV 89523				[redacted]	5
Employer Renown	Business 21 Locust St., Reno NV 89502				(775) 982-5000	

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑

If yes, state type, where and years held

N/A

N/A

N/A

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

N/A

N/A

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

N/A

Applicant's initial JLA

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes ☐ No ☑

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? Yes ☑ No ☐

20. Will you be employed fulltime with the pharmacy or wholesaler? Yes ☑ No ☐

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? Yes ☑ No ☐



Date of photograph 7/14/2020

Applicant's initial JLA

STATE OF NEVADA
ss.

COUNTY OF CLARK

I, JED LESTER BARTOLOME ANISCO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Janisco
Original Signature of Applicant

Subscribed and Sworn to before me this 14 day of
JULY 2020 JED LESTER BARTOLOME ANISCO

Chris Manolidis
Notary Public

(seal)

Notary Public - State Of Nevada
COUNTY OF CLARK
CHRIS MANOLIDIS
My Appointment Expires
April 1, 2024
No. 16-2192-1

Applicant's initial JLA

ADDITIONAL INFORMATION

Applicant's initial JLA

THE UNITED STATES OF AMERICA

No. [redacted]

CERTIFICATE OF NATURALIZATION

Personal description of holder as of date of naturalization:

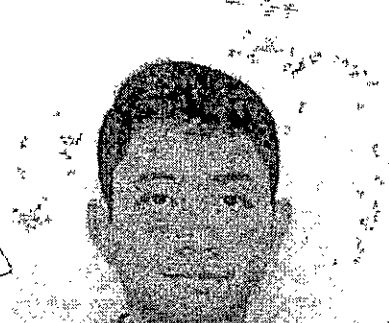
Date of birth: [redacted]

Sex: **MALE**

Height: **6** *feet* **0** *inches*

Marital status: **SINGLE**

Country of former nationality: **PHILIPPINES**



ALTERATION OR MISUSE OF THIS DOCUMENT IS A FEDERAL OFFENSE AND PUNISHABLE BY LAW

USCIS Registration No: **A059824113**

I certify that the description given is true, and that the photograph affixed hereto is a likeness of me.

(Complete and true signature of holder)

Be it known that, pursuant to an application filed with the Secretary of Homeland Security

at: **LAS VEGAS, NEVADA**

The Secretary having found that:

JED LESTER BARTOLOME ANISCO

residing at: **HENDERSON, NEVADA**

having complied in all respects with all of the applicable provisions of the naturalization laws of the United States, being entitled to be admitted as a citizen of the United States, and having taken the oath of allegiance at a ceremony conducted by

US DISTRICT COURT, DISTRICT OF NEVADA

at: **LAS VEGAS, NEVADA** *on:* **MAY 26, 2017**

such person is admitted as a citizen of the United States of America.

U. S. Citizenship and Immigration Services

DEPARTMENT OF HOMELAND SECURITY

FORM N-550 (REV. 10/12)

2159

10

RECEIVED 7-23-2020

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH_____

Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☑ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: The Medicine Shoppe LTC Pharmacy

Physical Address: 5801 Craig Dr., Ste. 130

City: Las Vegas, NV State: Zip Code: 89130 Telephone: (702) 268-8808

Fax: (702) 268-8848 Toll Free Number: N/A

E-mail: 2169@medicineshoppe.com

Website: www.medicineshoppe.com

Managing Pharmacist: Lacie Taketa License Number: 20359

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☑	☐ Long Term Care
☐	☑ Other: _____	☑	☐ Sterile Compounding
		☑	☐ Non Sterile Compounding
	All boxes must be checked	☑	☐ Mail Service Sterile Compounding
	For the application to be complete	☐	☑ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Mariana. A. S

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mariana Tadros

Print Name of Authorized Person

7/17/2020

Date

Board Use Only	Date Processed:_____	Amount: 500.00

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: N/A

Mailing Address: 11027 Sardinia Sands Dr.

City: Las Vegas State: NV Zip: 89141

Telephone: (702) 268-8808 Fax: (702) 268-8848

Contact Person: Mariana Tadros

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Mariana Tadros - [redacted] Spyglass Dr., Corona, CA 92883
Name Business Address

b) Wael Anwar - [redacted] Lion St., Rancho Cucamonga, CA 91730
Name Business Address

c) Chad Valencia - [redacted] Sardina, Las Vegas NV 89141
Name Business Address

d) N/A
Name Business Address

2) Provide the number of shares issued by the corporation. 5,000

3) What was the price paid per share? $0.00

List any physician shareholders and percentage of ownership.

Name: N/A %: N/A

Name: N/A %: N/A

Hours of Operation for the pharmacy:

Monday thru Friday 09:00 am 09:00pm Saturday N/A am N/A pm

Sunday N/A am N/A pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NV20191561333

Include with the application for a non publicly traded corporation continued

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I, Mariana Tadros

Responsible Person of The Medicine Shoppe LTC Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Mariana A S

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mariana Tadros
Print Name of Authorized Person

7/17/2020
Date

ACKNOWLEDGMENT

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

State of California
County of Riverside)

On July 17, 2020 before me, D. Antonio Martin Notary Public
(insert name and title of the officer)

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

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

WITNESS my hand and official seal.

D. ANTONIO MARTIN
Comm. #2239451
Notary Public·California
Riverside County
Comm. Expires Jan 26, 2022

Signature D. Antonio Martin (Seal)

Managing Pharmacist

Pharmacist Name: Jed Lester Anisco License #: 19983

Pharmacy Name: The Medicine Shoppe LTC Pharmacy

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☑
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☑
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☑

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature _____ Date April 5, 2021

STOCK TRANSFER LEDGER

NAME OF STOCKHOLDER	PLACE OF RESIDENCE	TIME BECAME OWNER	CERTIFICATES ISSUED		FROM WHOM SHARES WERE TRANSFERRED (If Original Issue Enter As Such)	AMOUNT PAID THEREON	DATE OF TRANSFER OF SHARES	TO WHOM SHARES ARE TRANSFERRED	CERTIFICATES SURRENDERED	
			CERTIF. NOS.	NO. SHARES					CERTIF. NOS.	NO. SHARES
Mariana Tadros	[redacted] Spyglass Dr. Corona, CA 92883	9/6/19	1	2000	Original					
Wael Anwar	[redacted] Lion Street Rancho Cucamonga CA 91730	9/6/19	2	2000	Original					
Arturo I. Valencia	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	9/6/19	3	1000	Original		07/15/20	Chad Valencia	3	1000
Chad Valencia	[redacted] Sardinia Sands Dr. Las Vegas, NV 89141	07/15/20	4	1000	Arturo Valencia	$1.00				

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, Barbara K. Cegavske, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **ALLIED HEALTH CARE SOLUTIONS, INC.**, as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 08/26/2019, and is in good standing in this state.

I further certify that the above DOMESTIC CORPORATION (78) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/29/2020.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B20200629891248
You may verify this certificate online at http://www.nvsos.gov

List of officers and directors

President	Mariana Tadros
Secretary	Mariana Tadros
Treasurer	Mariana Tadros
Director	Mariana Tadros

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 7/17/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

The Medicine Shoppe LTC Pharmacy - 5801 Craig Dr., ~~Unit B~~ STE. 130, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Tadros | Mariana | Awni Al Fakhouri
Last Name | First Name | Middle Name

Maiden name: "Mariana Alfakhouri"
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Spyglass Dr., Corona, CA 92833
Present Residence Address-Street or RFD | City | State/Zip

9194 Magnolia Ave., Riverside, CA 92503 Dates 04/2015 - Present
Present Business Address | City | State/Zip

Administration/Manager Dates 04/2018 - Present
Occupation

Phone: Residence [redacted]

Business (951) 977-8667

[redacted]
Date of Birth

Al Salt , Amman, Jordan
Place of Birth (City, County, State)

33 | [redacted] | Female
Age | Social Security Number | Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Light	119lbs	Slim	5'4"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No [redacted] Date 10/14/2015

Place Los Angeles, CA (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☑ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial M.T

A. **Current Marriage** 11/10/2013 (Date) Pasadena, Los Angeles, CA (City, County and State)

Spouse's full name (Maiden) Michael Tadros S.S. No. [redacted]

Date of Birth [redacted] Place of Birth Cairo, Egypt

Resident address [redacted] Spyglass Dr., Corona, CA 92833 (Street / City / State / Zip)

Telephone: Residence [redacted] Business (909) 542-9365

Spouse's employer The Medicine Shoppe Occupation Pharmacist / Pharmacy Owner

Address of employer 9675 Monte Vista Ave., Ste. A, Montclair, CA 91763 (Street / City / State / Zip)

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Edward Tadros	[redacted]	Newport Beach, CA	[redacted] Spyglass Dr., Corona, CA 92833
Ethan Tadros		Newport Beach, CA	[redacted] Spyglass Dr., Corona, CA 92833
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial M.T

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Awni Alfakhouri	[redacted]	[redacted] Spyglass Dr., Corona, CA 92833	Clerk
Mother	Raghda Alfakhouri		[redacted] Spyglass Dr., Corona, CA 92833	Home maker
Father-in-Law	Edward Tadros (deceased)		Cairo Egypt	Teacher
Mother-in-Law	Nariman Hanna		[redacted] Spyglass Dr., Corona, CA 92833	Teacher

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Hisham Alfakhouri	[redacted]	Alsalt, Jordan	Sales Representative
Spouse	Rita Dawoud		Alsalt, Jordan	Medical Assistant
	Hussam Alfakhouri		Alsalt, Jordan	Sales Representative
Spouse	Mera Fakhoury		Alsalt, Jordan	Preschool Principle
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	N/A	N/A	N/A	Yes ☐ No ☐
High School	Granite Hills	Apple Valley, CA	2002 - 2004	Yes ☑ No ☐
College University	La Sierra University	Riverside, CA	2007 - 2010	Yes ☑ No ☐
Other				Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science - Biology

College or university where obtained La Sierra University

Applicant's initial M.T

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☑
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial M.T

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
04/2015 - Present	[redacted] Spyglass Dr., Corona, CA 92883		
09/2013 - 03/2015	2494 Dakin Dr., Corona, CA 92882		
04/2008 - 09/2013	7024 Miami St., Riverside, CA 92506		
05/2002 - 04/2008	16421 Apple Valley Rd,. #4, Apply Valley, CA 92307		
07/1995 - 05/2002	Alsalt, Jordan		
N/A			
N/A			
N/A			
N/A			
N/A			
N/A			

Applicant's initial M.T

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

04/2018 - Present	The Medicine Shoppe - 9194 Magnolia Ave., Riverside, CA 92503	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
CEO	Administration and Management	Self
Title	Description of Duties	Name of Supervisor
06/2015 - 04/2018	The Medicine Shoppe - 10237 Magnolia Ave., Riverside, CA 92503	Business Closure
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Human Resources Associate	Assist with employee training, relations, benefits, compensation	Michael Tadros
Title	Description of Duties	Name of Supervisor
12/2013 -	Allergan - 2525 Dupont Dr, Irvine, CA 92612	Laid off
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Compounding Management Associate	Compound inventory, preparation, and data entry	Nady Mettais
Title	Description of Duties	Name of Supervisor
07/2013 - 12/2013	Adecco Medical Sciences - 2525 Dupont Dr, Irvine, CA 92612	Hired at Allergan
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Compounding Management Associate	Compound inventory, preparation, and data entry	Nady Mettias
Title	Description of Duties	Name of Supervisor
09/2010 - 08/2012	LLVare - 710 Brookside Ave, Redlands, CA 92373	Personal Reasons
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Research Technician	Isolation of RNA & DNA, measurements of mRNA & pre-mRNA	Yossouf Amaar
Title	Description of Duties	Name of Supervisor
01/2009 - 06/2010	La Sierra University - 4500 Riverwalk Pkwy, Riverside, CA 92505	Contract Ended
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Teacher Assistant	Assistance in office & lab classes for Physics & Biology	Eugene Joseph
Title	Description of Duties	Name of Supervisor
10/2004 - 01/2009	N/A	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Unemployed		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial M.T

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Rindala Obeid	Home	Loma Linda, CA 92354			[redacted]	12
Employer Kaiser	Business	9961 Sierra Ave, Fontana, CA 92335			(833) 574-2273	
Name Miriam Nagoulat	Home	San Bernardino, CA 92346			[redacted]	13
Employer Loma Linda University	Business	25455 Barton Rd., Loma Linda, CA 92354			(909) 558-4000	
Name Uyan Azia	Home	Eastvale, CA 92880			[redacted]	11
Employer Riverside University Health System	Business	4065 County Circle Dr., Riverside, CA 92503			(951) 358-5000	
Name Dina Wasef	Home	Corona, CA 92882			[redacted]	11
Employer Kaiser	Business	10800 Magnolia Ave, Riverside, CA 92505			(833) 574-2273	
Name Hamsa Azar	Home	Upland, CA 91784			[redacted]	10
Employer Kaiser	Business	Sierra Ave, Fontana, CA 92335			(833) 574-2273	

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☑ No ☐
If yes, state type, where and years held
Liquor - Irvine, CA - 2019
N/A
N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☑ No ☐
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

(Pharmacy; 04/2018 - Present; The Medicine Shoppe; 9194 Magnolia Ave., Riverside, CA 92503; California State Board of Pharmacy)
(Pharmacy; 02/2019 - Present; The Medicine Shoppe; 31946 Mission Trl., Ste. A-1, Lake Elsinore, CA 92530; California State Board of Pharmacy
Partner - Fady Mosaad - 3100 Van Buren Blvd., #924, Riverside, CA 92503)
(Restaurant; 11/2014 - Present ; Cafe 350 - 350 Commerce, Unit 150, Irvine, CA 92602
Partner - Gerges 704 Pointe Vista Ln., Corona, CA 92881)

Applicant's initial M.T

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☑ No ☐

AT



Date of photograph 7/2/2020

Applicant's initial MT

STATE OF California
ss.

COUNTY OF Riverside

I, Mariana Tadros, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Mariana A.
Original Signature of Applicant

Subscribed and Sworn to before me this 17 day of July 2020

D. Antonio Mtz.
Notary Public

(seal)

D. ANTONIO MARTIN
Comm. #2239451
Notary Public · California
Riverside County
Comm. Expires Jan 26, 2022

Applicant's initial M.T

N/A

Applicant's initial M-T

THE UNITED STATES OF AMERICA

No. [redacted]

ORIGINAL TO BE GIVEN TO THE PERSON NATURALIZED

CERTIFICATE OF NATURALIZATION

Personal description of holder as of date of naturalization

Date of birth [redacted]

Sex FEMALE

Height 5 feet 4 inches

Marital status MARRIED

Country of former nationality JORDAN



USCIS Registration No. [illegible]

I certify that the description given is true, and that the photograph affixed hereto is a likeness of me.

[illegible]

(Complete and true signature of holder)

Be it known that, pursuant to an application filed with the Secretary of Homeland Security

at: SAN BERNARDINO, CALIFORNIA

The Secretary having found that:

[illegible]

residing in: CORONA, CALIFORNIA

having complied in all respects with all of the applicable provisions of the naturalization laws of the United States, and having taken the oath of allegiance at a ceremony conducted by the

US DISTRICT COURT CENTRAL DISTRICT

LOS ANGELES, CALIFORNIA

OCTOBER [illegible]

[illegible]

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 07/16/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

The Medicine Shoppe LTC Pharmacy - 5801 Craig Dr., ~~Unit B~~ STE. 130, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name	First Name	Middle Name
Anwar	Wael	Nabil

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Lion St., Rancho Cucamonga, CA 91730
Present Residence Address-Street or RFD — City — State/Zip

1 World Way, Los Angeles, CA 90045 Dates 09/2012 - Present
Present Business Address — City — State/Zip

Flight Attendant Dates 06/2001 - Present
Occupation

Phone: Residence [redacted]

Business (800) 693-3582

[redacted]
Date of Birth

Cairo, Egypt
Place of Birth (City, County, State)

43 — Age

[redacted]
Social Security Number

Male
Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Light	185lbs		5'7"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No [redacted] Date 07/22/2005

Place Pomona, CA (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☑ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial WA

A. **Current Marriage** 05/21/2006 (Date) Mississauga, ON, Canada (City, County and State)

Spouse's full name (Maiden) Maria F. Kozman S.S. No [redacted]

Date of Birth [redacted] Place of Birth Cairo, Egypt

Resident address [redacted] Lion St., Rancho Cucamonga, CA 91730 (Street / City / State / Zip)

Telephone: Residence [redacted] Business N/A

Spouse's employer Self Occupation Homemaker

Address of employer [redacted] Lion St., Rancho Cucamonga, CA 91730 (Street / City / State / Zip)

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Paul Anwar	[redacted]	Glendora, CA	[redacted] Lion St., Rancho Cucamonga, CA 91730
Mina Anwar		Glendora, CA	[redacted] Lion St., Rancho Cucamonga, CA 91730
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial WA

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Nabil Awad	[redacted]	[redacted] Archiblad Ave., Rancho Cucamonga, CA 91701	Manager
Mother	Zeizaf Ibrahim		[redacted] Archiblad Ave., Rancho Cucamonga, CA 91701	Home Maker
Father-in-Law	Fayez Mousa Kozman		[redacted] Mohamad Abdalla St., Cairo, Egypt	Public Relations Manager
Mother-in-Law	Kamilia Abdelsayed		[redacted] Lion St., Rancho Cucamonga, CA 91730	Home Maker

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Sameh Awad	[redacted]	[redacted] Elder Eastwood Ave., Orange, CA 92689	Business Owner
Spouse	Maria Botrous		[redacted] Elder Eastwood Ave., Orange, CA 92689	Home Maker
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	College Patriarcal	Egypt	1981-1990	Yes ☑ No ☐
High School	College De La Salle	Egypt	1990 - 1993	Yes ☑ No ☐
College University	Helwan University	Egypt	1994 - 1998	Yes ☑ No ☐
Other	N/A			Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science - Commerence & Business Administration

College or university where obtained Helwan University

Applicant's initial WA

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ 'No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☑
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial WA

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
09/2012 - Present	[redacted] Lion St.,	Rancho Cucamonga,	CA 91730
01/2007 - 08/2012	8837 Grove Ave., #1403,	Rancho Cucamonga,	CA 91730
02/2005 - 12/2006	8722 Lomita Dr., #B,	Alta Loma,	CA 91701
02/2003 - 01/2005	10040 Placer St., #D,	Rancho Cucamonga,	CA 91730
06/2002 - 01/2003	271 Brevoort St.,	Kew Gardens,	NY 11415
01/2002 - 05/2002	83-33 118th St.,	Kew Gardens,	NY 11415
04/2001 - 12/2001	83-09 Talbot St., #PH-6E,	Kew Gardens,	NY 11415
01/2001 - 03/2001	9427 Cameron Ave.,	Rancho Cucamonga,	CA 91729
01/2000 - 12/2000	3730 Pacific Ave.,	Riverside,	CA 92509
10/1999 - 12/1999	1010 W. Badillo St.,	West Covina,	CA 91790
12/1994 - 09/1999	13 Kaitbay St.,	Heliopolis, Cairo,	Egypt

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

06/2001 - Present	Delta Airlines - 1 World Way, Los Angeles, CA 90045	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Flight Attendant	Guide and assist the safety and comfort of passengers	Jesse Rhodes
Title	Description of Duties	Name of Supervisor
12/2010 - Present	Miracle Medical Industries, Inc. - 1701 S. Vineyard Ave., #E, Ontario, CA 91761	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
CEO	Importing and Distribution of Medical Supplies	Self
Title	Description of Duties	Name of Supervisor
09/2013 - 12/2014	Delicare Medical Supplies - 2132 S. Grove Ave., #6, Ontario, CA 91761	Closure of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President	Distribution of Medical Supplies	Self
Title	Description of Duties	Name of Supervisor
03/2005 - 12/2010	Valero - 01 W. 6th St., Corona, CA 92882	Sale of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President/Officer	Manage, own, and operate gas station	Self
Title	Description of Duties	Name of Supervisor
01/2003 - 02/2005	Valaro - 5700 Atlantic Blvd., Maywood, CA 90270	Sale of Business
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
President/Officer	Manage, own, and operate gas station	Self
Title	Description of Duties	Name of Supervisor
01/2000 - 05/2001	Mobil - 6824 Valley Way, Riverside, CA 92509	Hired at Delta Airlines
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Manager	Managing employees and daily operations	Nagy Attalla
Title	Description of Duties	Name of Supervisor
06-1999 - 09/1999	Delta Bank - 1191 Kornich El Nile , Downtown , Cairo , Egypt.	Immigrated to USA
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Accountant	Process letter of credits to receive and send internationally	Tarek
Title	Description of Duties	Name of Supervisor
08/1998 - 05-1999	N/A	
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Unemployed		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial ..... WA .....

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Adel Ebeid	Home [redacted] Church St., Apt 106, Rancho Cucamonga CA 91730				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Ramy Barsoum	Home [redacted] Shelby P., Apt 136 Rancho Cucamonga, CA 91739				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Philip Youssef	Home [redacted] Melbourne Pl., Riverside CA 92508				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Marianna Tadros	Home [redacted] Spyglass Dr., Corona, CA 92883				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					
Name Michael Tadros	Home [redacted] Spyglass Dr., Corona, CA 92883				[redacted]	5
Employer The Medicine Shoppe	Business 9194 Magnolia ave Riverside CA, 92503					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑
If yes, state type, where and years held

N/A

N/A

N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

N/A

N/A

Applicant's initial WA

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑



Date of photograph 06/20/20

Applicant's initial WA

STATE OF Calfornia ss.

COUNTY OF San Bernardino

I, WAEL N. ANWAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

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

.....

.....
Notary Public

(seal)

See Attached
Notarial Certificate

Applicant's initial WA

CALIFORNIA JURAT

(CALIFORNIA GOVERNMENT CODE § 8202)

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

STATE OF CALIFORNIA
COUNTY OF San Bernardino

Subscribed and sworn to (or affirmed) before me on this 16 day of July, 2020,
by Wael Nabil Anwar, proved to me on the basis of
(Name of Signer(s))
satisfactory evidence to be the person(s) who appeared before me.

CONTESSA RENEA LEE
Notary Public - California
San Bernardino County
Commission # 2180146
My Comm. Expires Jan 16, 2021

Signature of Notary Public (Notary Seal)

ADDITIONAL OPTIONAL INFORMATION

Description of Attached Document

Title or Type of Document: Personal History Document Date: 7/16/2020

Number of Pages: 10 Signer(s) Other Than Named Above: N/A

Additional Information: N/A

N/A

Applicant's initial WA

THE UNITED STATES OF AMERICA

No. [redacted]

CERTIFICATE OF NATURALIZATION

Personal description of holder as of date of naturalization:

Date of birth: [redacted]

Sex: **MALE**

Height: **5** *feet* **7** *inches*

Marital status: **SINGLE**

Country of former nationality:

EGYPT



CIS Registration No. **A046835842**

I certify that the description given is true, and that the photograph affixed hereto is a likeness of me.

(Complete and true signature of holder)

Be it known that, pursuant to an application filed with the Secretary of Homeland Security

at: **LOS ANGELES, CALIFORNIA**

The Secretary having found that:

WAEL NABIL ANWAR

then residing in the United States, intends to reside in the United States when so required by the Naturalization Laws of the United States, and had in all other respects complied with the applicable provisions of such naturalization laws and was entitled to be admitted to citizenship, such person having taken the oath of allegiance in a ceremony conducted by the

US DISTRICT COURT CENTRAL DISTRICT

at: **POMONA, CALIFORNIA** *on:* **JULY 22, 2005**

that such person is admitted as a citizen of the United States of America.

Director, U. S. Citizenship and Immigration Services

IT IS PUNISHABLE BY U. S. LAW TO COPY, PRINT OR PHOTOGRAPH THIS CERTIFICATE, WITHOUT LAWFUL AUTHORITY.

DEPARTMENT OF HOMELAND SECURITY

FORM N-550 REV. 4/04

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 07-16-2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Pharmacy
Nature of License

The Medicine Shoppe LTC Pharmacy - 5801 Craig Dr., ~~Unit B~~ STE. 130, Las Vegas, NV 89130
Name and Address of Establishment for Which License Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Valencia (Last Name) | Chad (First Name) | Alexander (Middle Name)

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Sardinia Sands Dr., Las Vegas, NV 89141
Present Residence Address-Street or RFD | City | State/Zip

6432 Beckman Glen Ct., Las Vegas, NV 89141 Dates 10/2019 - Present
Present Business Address | City | State/Zip

Data Analyst/Scientist, Consultant Dates 10/2019 - Present
Occupation

Phone: Residence [redacted]
Business (626) 672-6902

[redacted]
Date of Birth

Whitter, Los Angeles, CA
Place of Birth (City, County, State)

37 (Age) | [redacted] (Social Security Number) | Male (Sex)

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Brown	Black	Tan	220lbs	Large	5'7"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☑ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's initial CV

MARITAL INFORMATION-Continued

A. **Current Marriage**.....
Date City, County and State

Spouse's full name (Maiden)..... S.S. No.....

Date of Birth..... Place of Birth.....

Resident address.....
Street City State Zip

Telephone: Residence..... Business.....

Spouse's employer..... Occupation.....

Address of employer.....
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
N/A			
N/A			
N/A			

B. Child Support Information:

Please mark the appropriate response:

☑ I am not subject to a court order for the support of child.

☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial.....

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Arturo Valencia	[redacted]	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	Business Development
Mother	Cristina Enrile		[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	Accountant
Father-in-Law	N/A			
Mother-in-Law	N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Robert Valencia	[redacted]	[redacted] Sardinia Sands Dr., Las Vegas, NV 89141	Teacher
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			
	N/A			
Spouse	N/A			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	GSE / Suzanne Middle School	Walnut, CA	09/1991 - 06/1996	Yes ☑ No ☐
High School	Walnut High School	Walnut, CA	09/1997 - 06/2000	Yes ☑ No ☐
College University	UCLA	Los Angeles, CA	09/2000 - 06/2003	Yes ☑ No ☐
Other				Yes ☐ No ☐

Type of degree obtained, if any Bachelor's of Science, Mathematics-Economics

College or university where obtained University of California, Los Angeles

Applicant's initial CV

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☑

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☑

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☐ No ☑ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A					
N/A					
N/A					

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☑ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☑

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☑

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☑

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☑
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☑
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☑ No ☐
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
Art Valencia	Father	Immigration Fraud	Los Angeles, CA	2008
N/A				
N/A				

Applicant's initial

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☑ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				
N/A				
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☑ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		
N/A		
N/A		
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
10/2019 - Present	[redacted] Sardinia Sands Dr.,	Las Vegas,	NV 89141
09/2018 - 10/2019	39-20 52nd St., Apr. 3F,	Woodside,	NY 11377
03/2013 - 09/2018	4657 Laurel Ridge Dr.,	Riverside,	CA 92509
09/2012 - 03/2013	11027 Sardinia Sands Dr.,	Las Vegas,	NV 89141
09/2009 - 09/2012	6432 Beckman Glen Ct.,	Las Vegas,	NV 89141
01/2007 - 09/2009	4657 Laurel Ridge Dr.,	Riverside,	CA 92509
09/2005 - 01/2007	39-20 52nd St., Apr. 3F,	Woodside,	NY 11377
06/2003 - 09/2005	304 Muirfield Ln.,	Walnut,	CA 91789
06/2002 - 06/2003	535 Gayley Ave.,	Los Angeles,	CA 90024
09/2000 - 06/2002	350 De Neve Dr.,	Los Angeles,	CA 90024
12/1994 - 09/2000	304 Muirfield Ln.,	Walnut,	CA 91789

Applicant's initial CW

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

05/2019 - 12/2019	Noble Desktop - 185 Madison Ave., New York, NY 10016	Moved to Las Vegas
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Instructor	Taught data science courses	Zach Cohen
Title	Description of Duties	Name of Supervisor
05/2018 - 05/2019	Codecademy - 575 Broadway, New York, NY 10012	Moved to New York
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Instructor	Taught data science courses	Tracy Teague
Title	Description of Duties	Name of Supervisor
10/2017 - Present	Freelance Data Scientist	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Data Scientist	Independent Data Projects	Self
Title	Description of Duties	Name of Supervisor
10/2004 - 09/2017	Owl Homecare Pharmacy - 13851 Garvey Ave Suite A Baldwin Park, CA 91706	Business Closure
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Analyst	Billing Analysis and Consulting	Cristina Valencia
Title	Description of Duties	Name of Supervisor
10/2001 - 10/2004	Unemployed	N/A
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A	N/A	N/A
Title	Description of Duties	Name of Supervisor
10/2000 - 10/2001	UCLA Access Control - 330 De Neve Dr, Los Angeles, California 90024	Focus on graduating
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Volunteer	Access Monitor Security for Droms	Junji Toshima
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor
N/A		
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
N/A		
Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial CV

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Jane Lagunilla	Home [redacted] White Sands Way, Arverne, NY 11692				[redacted]	15
Employer Memorial Sloan Kettaring	Business 16 E. 60th St., New York, NY 10022				(646) 888-6001	
Name Theresa Francisco	Home [redacted] White Sands Way, Arverne, NY 11692				[redacted]	30
Employer Retired	Business N/A					
Name Tony Chou	Home [redacted] Walnut Canyon Rd., Walnut, CA 91789				[redacted]	25
Employer LA-USC	Business 2051 Marengo St., Los Angeles, CA 90033				(323) 409-1000	
Name David Aure	Home [redacted] Scotch Pine Ridge, Yorba Linda, CA 92886				[redacted]	25
Employer Realtor	Business 5685 Scotch Pine Ridge, Yorba Linda, CA 92886				(714) 944-2933	
Name Brandon Nichols	Home [redacted] Overland St., Riverside, CA 92503				[redacted]	10
Employer Self-Employed	Business 3822 Overland St., Riverside, CA 92503				(951) 999-0339	

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other personís depository? Yes ☐ No ☑
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
N/A			
N/A			
N/A			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☑
If yes, state type, where and years held
N/A

N/A

N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☑
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.
N/A

N/A

N/A

Applicantís initial CV

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☑

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☑

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☑

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☑

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☑

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☑

ATTACH PHOTOGRAPH



Date of photograph 07-16-2020

Applicant's initial CW

STATE OF Nevada

ss.

COUNTY OF Clark

I, Chad Valencia, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent, and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 16th day of July 2020

Notary Public

STEPANIE PARLADE
Notary Public - State of Nevada
County of Clark
APPT. NO. 18-3090-1
My App. Expires July 12, 2022

Applicant's initial

ADDITIONAL INFORMATION

N/A

Applicant's initial

GEORGE S. CARDONA
United States Attorney
THOMAS P. O'BRIEN
Assistant United States Attorney
Chief, Criminal Division
ELISA FERNANDEZ (Cal. State Bar No. 172004)
Assistant United States Attorney
Public Corruption & Civil Rights Section
1300 United States Courthouse
312 North Spring Street
Los Angeles, California 90012
Telephone: (213) 894-7383
Facsimile: (213) 894-6436
E-mail: Elisa.fernandez@usdoj.gov

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ARTURO VALENCIA, Defendant.	CR No. 05-0002-PA STIPULATION TO CONTINUE DEFENDANT ARTURO VALENCIA'S SENTENCING HEARING Sentencing Date: July 20, 2007 Proposed Date: January 7, 2008

Plaintiff United States of America, by and through its counsel of record, the United States Attorney for the Central District of California, defendant Arturo Valencia ("Valencia"), individually and through his counsel, Federal Public Defender Nadine Hettle, hereby agree and jointly stipulate, and request that the court continue defendant Valencia's sentencing hearing from July 20, 2007, at 8:30 a.m., to January 8, 2008, at 8:30

///

///

a.m. for the following reasons:

1. On February 14, 2005, defendant Valencia pled guilty to a two-count information of conspiring to commit immigration fraud and his participation in an immigration fraud scheme which involved the law corporation of Korenberg, Abramowitz & Feldun ("KAF").

2. After defendant entered his guilty plea, the government continued its investigation into the illegal activities of KAF in relation to KAF's partners, associates and employees who participated in an immigration fraud scheme. To that end, defendant agreed to assist the government in completing its investigation, and has been doing so since entering his guilty plea.

3. Two partners of the KAF law firm, Daniel Korenberg ("Korenberg") & Steven Rodriguez ("Rodriguez"), have been indicted on presenting false immigration documents and petitions to the Immigration and Naturalization Service ("INS") in violation of Title 18, United States Code, Sections 371, 1001, and 1546(a). Korenberg and Rodriguez are set to proceed to trial on October 16, 2007.

4. Several defendants are scheduled to be sentenced in November and December 2007. Defendant Valencia's cooperation may be needed to prepare for those sentencings.

5. Defendant presently is on bond and has fully complied with all of the terms of pretrial release. Neither defendant nor defendant's counsel object to a continuance of the sentencing in this matter. Therefore, the parties request that defendant's sentencing date be continued to December 3, 2007 to provide

defendant further opportunity to cooperate and for the government to evaluate the scope and extent of defendant's cooperation and file a Section 5K1.1 motion, if warranted. The parties also request a continuance in the time to respond to the Presentence Report, and agree to serve the Probation Department their respective response by hand delivery.

Accordingly, the parties jointly request that the sentencing in this matter should be continued from July 20, 2007 to January 8, 2008, at 8:30 a.m.

June ___, 2007

Respectfully submitted

GEORGE S. CARDONA
United States Attorney

ELISA FERNANDEZ
Assistant United States Attorney

Attorneys for Plaintiff
United States of America

June ___, 2007

ARTURO VALENCIA
Defendant

June ___, 2007

NADINE HETTLE
Attorney for Defendant
ARTURO VALENCIA

GEORGE S. CARDONA
United States Attorney
THOMAS P. O'BRIEN
Assistant United States Attorney
Chief, Criminal Division
ELISA FERNANDEZ (Cal. State Bar No. 172004)
Assistant United States Attorney
Public Corruption & Civil Rights Section
1300 United States Courthouse
312 North Spring Street
Los Angeles, California 90012
Telephone: (213) 894-7383
Facsimile: (213) 894-6436

Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. ARTURO VALENCIA, Defendant.	CR No. 05-0002-PA [PROPOSED] ORDER REGARDING STIPULATION TO CONTINUANCE SENTENCING HEARING FOR DEFENDANT ARTURO VALENCIA Sentencing Date: July 20, 2007 Proposed Date: January 7, 2008

GOOD CAUSE HAVING BEEN SHOWN in the parties' stipulation to continue the sentencing in the above-entitled matter from July 20, 2007 to January 7, 2008, at 8:30 a.m., IT IS FOUND AND ORDERED that the sentencing in this matter is continued from July 20, 2007 to January 7, 2008, at 8:30 a.m. IT IS FURTHER ORDERED THAT Defendant Arturo Valencia appear on January 8, 2008,

///

///

///

at 8:30 a.m. in the courtroom of the Honorable Percy Anderson located at 312 N. Spring Street, Los Angeles, California, Courtroom 15.

DATED: June __, 2007

THE HON. PERCY ANDERSON
United States District Judge

Submitted By:

ELISA FERNANDEZ

defendant further opportunity to cooperate and for the government to evaluate the scope and extent of defendant's cooperation and file a Section 5K1.1 motion, if warranted. The parties also request a continuance in the time to respond to the Presentence Report, and agree to serve the Probation Department their respective response by hand delivery.

Accordingly, the parties jointly request that the sentencing in this matter should be continued from July 20, 2007 to January 8, 2008, at 8:30 a.m.

June ___, 2007

Respectfully submitted

GEORGE S. CARDONA
United States Attorney

ELISA FERNANDEZ
Assistant United States Attorney

Attorneys for Plaintiff
United States of America

June ___, 2007

ARTURO VALENCIA
Defendant

June ___, 2007

NADINE HETTLE
Attorney for Defendant
ARTURO VALENCIA

FEDERAL PUBLIC DEFENDER
321 East 2nd Street
Los Angeles, California 90012-4202

Telephone (213) 894-2854
Facsimile (213) 894-0081

FACSIMILE TRANSMISSION COVER SHEET

Date Sent:

TO:

NAME: Arturo Valencia

FAX #: 951-727-0696 **VOICE #:**

Number of Pages to Follow: 5

FROM: Nadine Hettle

COMMENTS: Art, just return the signature page (p. 3)

IN EVENT OF TRANSMISSION ERROR OR FOR VOICE COMMUNICATION

FAX (213) 894-0081 or CALL (213) 894-2854

THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL NAMED ABOVE. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE. THANK YOU.

2 attorneys charged with work visa fraud

The immigration lawyers allegedly filed false applications for foreign nationals employed at their firm, and perhaps for others.

By Anna Gorman
Times Staff Writer

Two local immigration attorneys have been charged with fraud after allegedly filing false employment visa applications for 14 foreign nationals working for their firm, according to a federal grand jury indictment released Thursday.

The lawyers, of ASK Law Group in Sherman Oaks, filed the fraudulent applications and paid their employees in cash while awaiting approval for the visas, according to the indictment. Investigators believe the attorneys also filed false visa applications on behalf of hundreds of other foreigners looking for work at other companies.

"This is the largest immigration fraud probe ever mounted against a Los Angeles-area law firm," said Jennifer Silliman, deputy special agent in charge of the local office of Immigration and Customs Enforcement.

The indictment charges Daniel Korenberg, a senior partner at the law firm, and Steven James Rodriguez, a senior associate, with visa fraud and conspiracy to commit visa fraud. Korenberg faces a possible sentence of 225 years in federal prison. Rodriguez faces up to 15 years in prison.

Another partner in the firm, Philip Abramowitz, 53, has already pleaded guilty to conspiracy and visa fraud.

The indictment accused the men of committing fraud between 2000 and 2003.

To obtain an employment visa for a foreign worker, a company must prove it cannot find a qualified U.S. employee to fill a specific job. The H-1B visas are limited to foreign workers with at least a bachelor's degree. Firms must pay foreign workers the prevailing wage.

Investigators said Korenberg, 57, and Rodriguez, 40, wrote false job titles and salaries on the visa applications, citing jobs that didn't exist. They also allegedly lied about the foreigners' work experience.

The fake job titles included accountant, human resources specialist and systems analyst/programmer. The employees were actually doing secretarial work, investigators said.

Several were here on visitors' visas, which did not allow them to work, agents said.

U.S. Citizenship and Immigration Services plans to review all the visa applications that are suspect, said spokeswoman Marie Sebrechts. If applicants were complicit in any fraud, their visas could be revoked, she said.

The ASK Law Group is based in Sherman Oaks, but has offices in Los Angeles, San Diego, San Francisco and Las Vegas. According to the firm's website, lawyers provide services to individuals, small businesses and large corporations.

Because the defendants are attorneys, Silliman said, they know how to work the system and get around loopholes.

"It's always disturbing when attorneys manipulate the system for financial gain," said Thom Mrozek, spokesman for the U.S. attorney's office in Los Angeles.

Korenberg, Abramowitz and Rodriguez did not return calls for comment. Korenberg and Rodriguez are scheduled to appear in U.S. District Court in Los Angeles on March 29.

The firm had a decent reputation, so the charges were shocking, said John Ayala, vice chairman of the Southern California chapter of the American Immigration Lawyers Assn.

"We hope the allegations are not true," Ayala said. "If they are found true, I think it's an aberration. It doesn't reflect the immigration bar of Southern California."

anna.gorman@latimes.com

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date April 5, 2021

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Designated Representative for The Medicine Shoppe
Nature of Pharmacy or Wholesaler

The Medicine Shoppe 5801 W. Craig Rd #130 Las Vegas, NV 89130
Name and Address of Business for Which Designated Representative Is Requested

N/A
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Last Name	First Name	Middle Name
Taketa	Lacie	Keiko

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise): N/A

Present Residence Address-Street or RFD	City	State/Zip
[redacted] E Starr Ave. #185	Las Vegas	NV / 89183

Present Business Address	Dates	City	State/Zip
N/A			

Present Position with the Pharmacy or Wholesaler	Dates	Phone: Residence
N/A		[redacted]

Business N/A

Date of Birth	Place of Birth (City, County, State)
[redacted]	Hilo, Hawaii, HI

Age	Social Security Number or ITIN	Sex
33	[redacted]	Female

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Dark brown	Dark brown	Fair	120 lbs.	Normal	5'1"

Scars, tattoos or distinguishing marks and/or characteristics Back & ankle tattoo

Are you a citizen of the United States? (Yes) No If alien, registration No N/A

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

(Single) Married Separated Divorced Widowed Engaged

Applicant's initial VT

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address

Contact person

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Lance Taketa	[redacted]	[redacted] Manono St. #102 Hilo, HI 96720	VP Real Estate Appraiser
Mother	Lisa Toyofuku		[redacted] Iwalani St. Hilo, HI 96720	Court Clerk to Judge Greg K. Nakamura
Father-in-Law	N/A			
Mother-in-Law	N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Landon Taketa (brother)	[redacted]	[redacted] Kanunu St. #1519 Honolulu, HI 96814	Food Safety Specialist
Spouse	N/A			
	Lyndee Taketa (sister)		[redacted] Spreckels Lane Redondo Beach, CA 90278	Psychologist
Spouse	Daniel Mendoza-Cenner		" "	Personal Trainer Event Promoter
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Waiakeawaena/Waiakea Intermediate	Hilo, HI	1994-2002	(Yes) No
High School	Waiakea High School	Hilo, HI	2002-2006	(Yes) No
College University	University of Hawaii at Hilo	Hilo, HI	2006-2012	(Yes) No
Other	Rosemun University of Health Sciences College of Pharmacy	Henderson, NV	2016-2019	(Yes) No

Type of degree obtained, if any Bachelor of Arts in Biology, Doctor of Pharmacy

College or university where obtained University of Hawaii at Hilo, Rosemun University of Health Sciences, College of Pharmacy

Applicant's initial VT

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ~~No~~ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ~~No~~ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
March 1988 - Feb 2016	563 Iwalani St.	Hilo	HI
Feb 2016 - Sept. 2020	1290 W. Horizon Ridge Pkwy #2427	Henderson	NV
Sept. 2020 - Present	[redacted] E Starr Ave #185	Las Vegas	NV

Applicant's initial VT

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
May 2017	Walgreens Pharmacy 9300 W. Sahara Ave, Las Vegas, NV 89117	160 hours
Title	**Description of Duties**	**Name of Supervisor**
Intern Pharmacist	Took in new prescription orders, blood pressure screenings, Administered immunizations, assisted with inventory	Monna Valle
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Oct. 2016	CVS Pharmacy 7265 N. Aliante Pkwy, North Las Vegas, NV 89084	136 hours
Title	**Description of Duties**	**Name of Supervisor**
Intern Pharmacist	Processed, filled, & transferred prescriptions Follow up doctor & patient phone calls.	Jessica Lechner
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
July 2016	Smith's Food & Drug Pharmacy 10616 S. Eastern Ave, Henderson, NV 89052	~ 250 hours
Title	**Description of Duties**	**Name of Supervisor**
Tech in training/Intern	Administered immunizations, patient counseling Transferred & took in new prescriptions	Star Rosario
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Feb. 2013	CVS Pharmacy 555 Kilauea Ave, Hilo, HI 96720	~ 4160 hours
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Technician	Processed & filled prescription orders, trained new employees, Assisted in inventory control	Ann Togashi
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Number of Employed Hours**
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial VT

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes — (No)

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes — (No)

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes — (No)

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes — (No)

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes — (No)

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? (Yes) — No

20. Will you be employed fulltime with the pharmacy or wholesaler? (Yes) — No

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? (Yes) — No



Date of photograph April 8, 2021

Applicant's initial VT

ADDITIONAL INFORMATION

I was involved in a traffic accident on Aug. 15, 2010. Based on the arresting officer's initial suspicion, an investigation for Negligent Injury 2nd was initiated, however, I was never charged thereafter.

On March 30, 2016, I completed and mailed an application to the Hawaii Criminal Justice Data Center, Department of the Attorney General, Expungement Section.

I have attached a copy of the Hawaii Criminal Justice Data Center Criminal background check indicating no conviction.

Applicant's initial LT

eCrim Certified Record

Data Generated: 03/30/2016

Validation Code: RH4HzCP1yEbw.I

https://ecrim.ehawaii.gov/ahewa/validate.do

Search Criteria: Last Name = TAKETA, First Name = LACIE, Soc Sec No = ***-**-6226, Date of Birth = **/**/1988, Sex = Female

No Criminal Convictions Found.

* IMPORTANT: The information furnished is based upon the descriptive information you have provided. Therefore it is your responsibility to carefully verify the information returned and match it against your search criteria. Furthermore, the search is limited to conviction data and data relating to cases in which the defendant is acquitted, or charges are dismissed, by reason of physical or mental disease, disorder or defect, under chapter 704, HRS, as maintained by the Hawaii Criminal Justice Data Center and does not include data maintained by the FBI or other states.

Because the criminal history records are constantly being updated, a new criminal history record check should be obtained for each subsequent use. Every effort is made to insure the accuracy of this information. Any disputes should be addressed separately with the Hawaii Criminal Justice Data Center.

This eCrim record has a unique validation number located on the top of the report. Records can be validated for up to sixty days from the date of purchase by visiting (free of charge) the validation service (https://ecrim.ehawaii.gov/ahewa/validate.do) and enter the validation number in the appropriate box.

11

11A

RECEIVED 6/16/2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Pharmacy Shop Inc. DBA: Ed Snell's Pharmacy Shop + Oxygen

Physical Address: 1015 E. Young St.

Mailing Address: _____

City: Pocatello State: Id Zip Code: 83201

Telephone: 208 232 0049 Fax: 208 232 3963

Toll Free Number: _____ (Required per NAC 639.708)

E-mail: ben@edsnellspharmacy.com Website: www.edsnellspharmacy.com

Managing Pharmacist: Toni Cantrell License Number: P5939

TYPE OF PHARMACY AND **SERVICES PROVIDED**

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☒	☐ Retail	☐	☒ Off-site Cognitive Services
☐	☒ Hospital (# beds_____)	☐	☒ Parenteral **
☐	☒ Internet	☐	☒ Parenteral (outpatient)
☐	☒ Nuclear	☐	☒ Outpatient/Discharge
☐	☒ Ambulatory Surgery Center	☐	☒ Mail Service
☒	☐ Community	☐	☒ Long Term Care
☐	☒ Other: _____	☒	☐ Sterile Compounding **
		☒	☐ Non Sterile Compounding
		☒	☐ Mail Service Sterile Compounding **
		☐	☒ Other Services: _____

All boxes must be checked
For the application to be complete

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Benjamin E Snell

Original Signature of Person Authorized to Submit Application, no copies or stamps

Benjamin E. Snell

Print Name of Authorized Person

6-11-2020

Date

Board Use Only Date Processed: JUN 17 2020 Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: Benjamin E. Snell

Business Name: Pharmacy Shop Inc. DBA: Ed Snell's Pharmacy Shop + Oxygen

Current Business Address: 1015 E. Young St.

City: Pocatello State: Id Zip Code: 83201

Telephone: 208-232-0649 Fax: 208-232-3963

List any physician shareholders and percentage of ownership.

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Hours of Operation for the pharmacy:

Monday thru Friday 9:30 am 6:30 pm Saturday 10 am 2 pm

Sunday Ø am Ø pm 24 Hours ✓

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Benjamin E. Snell

Responsible Person of Pharmacy Shop Inc. DBA: Ed Snell's Pharmacy Shop + Oxygen hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Benjamin E Snell

Original Signature of Person Authorized to Submit Application, no copies or stamps

Benjamin E. Snell

Print Name of Authorized Person

6.11.2020

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Idaho)
) ss.
Bannock COUNTY)

I, Benjamin E Snell, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for Ed Snell's Pharmacy Shoppe Oxygen (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Benjamin E. Snell, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Benjamin E Snell
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
11 day of June, 2020

NOTARY PUBLIC

STEPHANIE OLSEN
NOTARY PUBLIC
COMM NO. 60662
STATE OF IDAHO

November 19, 2021

Posted April 1, 2020

Idaho State Board of Pharmacy

1199 W Shoreline Lane Ste 303 Boise, Idaho 83702-9103 http://bop.idaho.gov
P.O. Box 83720 Boise, Idaho 83720-0067 208.334.2356 208.334.3536 fax

April 8, 2020

RECEIVED
APR 12 2020
NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521

CERTIFICATION

This is to certify that a search of the available records of the Idaho State Board of Pharmacy indicates the following:

ED SNELLS PHARMACY SHOP
1015 E YOUNG ST
POCATELLO, ID 83201

LICENSE TYPE:	RETAIL PHARMACY
LICENSE NUMBER:	801RP
ORIGINAL DATE ISSUED:	06/17/2002
CURRENT STATUS:	Active
DISCIPLINARY ACTION:	None
EXPIRATION DATE:	12/31/2020

If disciplinary action is indicated, details will be made available from the public file upon written request.

By: Cathy Hutson
Title: Licensing Specialist

IDAHO STATE BOARD OF PHARMACY

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** D3324

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Marley Drug, Inc.

Physical Address: 5008 Peters Creek Pkwy

Mailing Address: 5008 Peters Creek Pkwy

City: Winston-Salem State: NC Zip Code: 27127

Telephone: 336-771-7672 Fax: 336-771-9921

Toll Free Number: 800-286-6781 (Required per NAC 639.708)

E-mail: compliance@medicure.com Website: www.marleydrug.com www.marleygenerics.com

Managing Pharmacist: Christopher Gray Holler License Number: 15441

TYPE OF PHARMACY AND **SERVICES PROVIDED**

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds____)	☐	☑ Parenteral **
☐	☑ Internet (Patient refills only)	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting.**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☑ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

JK

Original Signature of Person Authorized to Submit Application, no copies or stamps

James Kinley

Print Name of Authorized Person

Nov 16, 2020

Date

Board Use Only Date Processed:_____ Amount: _____

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: North Carolina

Parent Company if any: Marley Drug, Inc.

Mailing Address: 5008 Peters Creek Pkwy

City: Winston-Salem State: NC Zip: 27127

Telephone: 204-487-7412 Fax: 204-487-7412

Contact Person: James Kinley

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Marley Drug, Inc is 100% owned by Medicure Pharma Inc. 200-116 Village Blvd Princeton NJ 08540
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1,000

3) What was the price paid per share? $ 10,300

4) What date did the corporation actually receive the cash assets? December 17th 2020

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: N/A %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 9 pm Saturday 9 am 5 pm

Sunday 9 am 5 pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: NA

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, James Kinley

Responsible Person of Marley Drug, Inc

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

James Kinley
Print Name of Authorized Person

Nov 9/2020
Date

NV

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF North Carolina)
) ss.
Forsyth COUNTY)

I, James Kinley, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO for Marley Drug, Inc (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, James Kinley, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

JK
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
18 day of March, 2020.

NOTARY PUBLIC

Ownership Information

The pharmacy is 100% owned by Marley Drug, Inc.

The officers of Marley Drug Inc. are:

1. Albert Friesen- CEO
2. James Kinley - CFO
3. Neil Owens - President and COO

Marley Drug, Inc. is 100% Owned by Medicure Pharma Inc.

The officers of Medicure Pharma Inc. are:

1. Albert Friesen – President
2. James Kinley – Secretary

Permit #: 14570

NORTH CAROLINA BOARD OF PHARMACY

2021 Pharmacy

This is to certify that

Marley Drug, Inc.

5008 Peters Creek Pkwy Winston-Salem, NC 27127 Forsyth

Has been renewed for the year ending December 31st 2021, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Christopher Gray Holler (#15441)

Ashley H. Duggins

PRESIDENT

12/17/2020
Issued

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

North Carolina Board of Pharmacy

License Verification

Only the top 250 records are shown

This serves as Primary Source Verification of the credential issued by the North Carolina Board of Pharmacy

Name:

Marley Drug, Inc.

Permit Number:

14570

Address:

5008 Peters Creek Pkwy

Permit Status:

Active

City:

Winston-Salem

Issue Date:

12/17/2020

State/Zip:

NC 27127

Expire Date:

12/31/2021

Manager:

Christopher Gray Holler

Discipline:

No

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

MARLEY DRUG, INC.

is a corporation duly incorporated under the laws of the State of North Carolina, having been incorporated on the 13th day of February, 2002, with its period of duration being Perpetual.

I FURTHER certify that, as of the date set forth hereunder, the said corporation's articles of incorporation are not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation is not administratively dissolved for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by N.C.G.S. 55-16-22 has been delivered to the Secretary of State; and that the said corporation has not filed articles of dissolution as of the date of this certificate.

Scan to verify online.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 19th day of April, 2021.

Elaine F. Marshall

Secretary of State

Certification# 110266415-1 Reference# 17392057- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

marleydrug.com
1.800.286.6781

NC licensed pharmacy, permit number 8320. All drugs are FDA approved, and purchased from state/federally licensed wholesalers.

10/16/2020

Dear *State Board of Pharmacy,*

History Statement of Disciplinary Action is below. Please see attached sheets for discipline summary, as well as corporate officer discipline.

History Statement of Disciplinary Actions

In July of 2011 we launched our "Extended Supply Generic Drug Program" that provided affordable generic drugs. Our marketing efforts were initially directed at North Carolina providers via an exhibit booth at medical conferences. It was at those conferences that we started getting interest from providers outside of NC. Based on that doctor interest, we obtained our first non-resident permits in SC and FL.

As our program was gaining acceptance by patients and physicians, it was while pursuing our VA non-resident permit that I learned that some states require a PIC licensed in that state prior to issuing a permit. It was shortly after that I realized we were on to something, and we needed to start seeking our non-resident permits for as many states as possible. To do that, I started printing the applications for all 50 states.

To get as many licenses as quickly as possible, I initially separated the 47 applications into two piles, one "easy" and one "hard" (State licensed PIC required), and over a period of months we obtained all the easy permits, many of which went unused as we had not yet attracted any interest from them.

During the years from 2011 to 2013 we were very diligent about what states we were licensed in and turned down a great many requests from patients and physicians from unlicensed states. I can't tell you exactly what date we started making "exceptions" but it was in the beginning of 2014 I believe that at a patient's urging we gave in and shipped it to him without the license. After that, I rationalized "well, we are getting the licenses as fast as we can, we'll get it eventually, and if the doctor sends us the prescription we'll fill it." Needless to say, that is a decision I regret.

In late 2015, it became clear the outside interest was growing faster than my capability to get all the outstanding PIC requires licenses. It took a while to find but in February of 2016, I hired another pharmacist who, as part of his employment, would seek out the 20 remaining licenses via reciprocity "as fast as possible." His name is R. Brent Clevenger and to date he has been able to get about 1 new license per month. By December 2017, Marley Drug had obtained all nonresident licenses in all states, including the District of Columbia. Of note, Massachusetts does not require a nonresident permit to this date.

In December of 2016 we had an inspection from the NC Board of pharmacy. We initiated the inspection request secondary to states requirement for a current inspection as part of their application. During the inspection, it was determined

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

EXTENDED SUPPLY
MARLEY DRUG
GENERIC DRUG PROGRAM™

marleydrug.com
1.800.286.6781

NC licensed pharmacy, permit number 8320. All drugs are FDA approved, and purchased from state/federally licensed wholesalers.

PIEDMONT BUSINESS ETHICS AWARD
2013 WINNER

BBB
ACCREDITED BUSINESS

2017 & 2018 WINNER
BEST PHARMACY
JOURNAL
READERS CHOICE

that we did not have all necessary permits. The investigator requested shipping reports for the states that we had shipped to that we were not licensed. We provided the reports. We also stopped shipping immediately to any of those states, until we could obtain the non-resident permit. During the months after the inspection, dispensing pharmacists were asked to remember which states we could ship to and which states we could not. Despite our efforts, a few prescriptions were inadvertently shipped into the states we were not licensed.

My passion for our generic drug program has always been about getting our generic medications in the hands of patients at a price they can afford, and that passion got the better of me in terms of the "hard" (PIC) licenses. It was never my intent to simply ignore the rules, but I admit that I failed to maintain the patience to do it properly.

CURRENT EFFORTS:

We have set internal policies to NOT ship any controlled substances, refrigerated items or compounded medications. While we've never compounded any sterile or complex prescriptions, we made it a store policy to not do ANY compounds (except reconstitution) as of 5/1/2017.

In March 2019, we implemented a multi-level computerized check system to ensure no medications are shipped to the states without permits. When reviewing our past deficiencies, we recognized human error and poor communication/understanding to be an issue. While we can never eliminate all human errors, we believe this check is helping us achieve better compliance.

In February 2019, pharmacist/owner Elizabeth Marley, PharmD changed employment to start as Marley Drug Compliance Coordinator. She will focus on maintaining compliance with resident and nonresident state regulations for all Marley Drug permits.

Respectfully submitted,

Dave Marley, PharmD.

CEO

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

MARLEY DRUG™
Generics you can afford, delivered to your door.

DAVID MARLEY DISCIPLINARY HISTORY

Date	Case #	Action
March 19, '19		North Carolina Board of Pharmacy Consent Order Determined Marley had unlawfully dispensed and shipped medications into 28 states in which the pharmacy lacked a license to operate **Action: License suspended for 54 weeks, stayed for two years after 2-week active suspension on conditions.**
April 12, '19	194911	Virginia Department of Health Professions Order of Mandatory Suspension NCBOP notified Virginia DOHP Marley had mailed prescriptions to residents of Virginia without permit. **Action: License suspended.**

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: DAVID MARLEY (License No. 12343)	)	**CONSENT ORDER**

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for February 18, 2019 and, after appropriate notice, was heard on that day by Board Member Gene Minton at the office of the Board. Respondent David Marley (hereinafter "Respondent" or "Marley") was present and represented by counsel Crystal Carlisle. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that he waives his right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by his consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent David Marley is, and was at all relevant times referred to herein, the holder of License No. 12343 and the pharmacist-manager at Marley Drug, Inc., located at 5008 Peters Creek Parkway, Winston-Salem, North Carolina (Permit No. 27127) ("the Pharmacy"). Marley is, and was at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. Between December 18, 2013 and April 3, 2018, pharmacists at the Pharmacy, acting under the supervision of Marley as pharmacist-manager, unlawfully dispensed and shipped prescriptions into Alabama, Arizona, Arkansas, California, Colorado, the District of Columbia, Georgia, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Utah, Vermont, West Virginia and Wyoming at times when the Pharmacy did not have a permit in those states. Marley himself was the dispensing pharmacist on approximately twelve percent of these prescriptions.

4. Included among these prescriptions, between December 8, 2014 and March 8, 2017, were 33 controlled substance prescriptions that were unlawfully dispensed and shipped into Alabama (eleven schedule IV prescriptions), Arizona (five schedule III and IV prescriptions), California (ten schedule IV prescriptions), Georgia (one schedule IV prescription), Maryland (three schedule IV prescriptions), and Tennessee (two schedule III and IV prescriptions) under the supervision of Marley. These controlled substances were dispensed at times when the Pharmacy did not have a permit in those states and was not registered to dispense controlled substances into those states. Marley and the Pharmacy also did not report to those states' controlled substance prescription monitoring programs, as required by law. Marley himself was the dispensing pharmacist on five of these prescriptions unlawfully dispensed and

shipped into Alabama (one schedule IV prescription), Arizona (two schedule IV prescriptions) and California (two schedule IV prescriptions).

5. Marley testified that he had actual knowledge that the Pharmacy did not hold a permit in these states when the drugs were unlawfully dispensed and shipped, except for two states (Alabama and Maine) where he testified that, at least at certain times, he believed that the Pharmacy had a permit when its permit had actually lapsed. However, the Board finds that it was unreasonable for Marley to believe that the Pharmacy had a permit in Alabama or Maine at any point when the Pharmacy did not have a permit, because he was legally responsible for assuring that the Pharmacy had a current permit before shipping, he did not have a current permit from those states in his possession, and publicly available information would have revealed that the Pharmacy did not have an active permit in those states at those times. Moreover, on January 9, 2018, Marley received notification from the Maine Board that (the Board finds) did or should have informed him that the Pharmacy's Maine permit had not been renewed for 2018, but Marley nevertheless continued to ship into Maine until the permit was actually renewed on April 4, 2018.

6. As a mitigating factor as to shipments after December 14, 2016, on that date, the Pharmacy and Marley implemented remedial measures to attempt to ensure that prescriptions were not shipped into Arizona, Arkansas, California, the District of Columbia, Idaho, Louisiana, Maryland, Michigan, Montana, Nebraska, Oklahoma, Oregon and West Virginia until permits were secured. These measures did dramatically reduce the number of shipments over the prior time when the Pharmacy and Marley intended to ship without permits, but the Pharmacy still did make a relatively small number of unlawful shipments despite these efforts.

7. Between March 2016 and July 2017, the Pharmacy, and Marley as its pharmacist-manager, regularly and unlawfully held the Pharmacy out in radio advertising as a permitted pharmacy in certain states at times when, in fact, it was not permitted to operate as a pharmacy. These violations are as follows:

a. In March 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the Commonwealth of Pennsylvania by adverlising on 63 occasions on a radio station in Pittsburgh;

b. Between July and September 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Illinois by advertising on 53 occasions on radio stations in Chicago;

c. Between July and December 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of California by advertising on 707 occasions on radio stations in Los Angeles, Sacramento and San Francisco;

d. During November and December 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Louisiana by advertising on 200 occasions on radio stations in New Orleans;

e. During December 2016 and January 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Oregon by advertising on 170 occasions on a radio station in Portland;

f. Between February and July 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Alabama by advertising on 79 occasions on radio stations in Gadsden and Mobile;

g. Between March and June 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Arkansas by advertising on 79 occasions on a radio station in Fort Smith; and

h. In June 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Michigan by advertising on 36 occasions on a radio station in Grand Rapids.

All advertisements run on and before December 14, 2016 were intentionally placed by Marley and the Pharmacy in states in which the Pharmacy was not permitted. However, as a mitigating

factor, the Board finds that – after December 14, 2016 – Marley Drug had instructed its advertising agency not to run advertising in certain states at the times of certain advertisements, but the advertising was run in violation of these instructions. This mitigating factor applies only to eighteen (18) of the advertisements in California and eighteen (18) of the advertisements in Louisiana on December 15 and 16, 2016; thirty-six (36) of the advertisements in Alabama from July 3 to 7, 2017; and all of the advertisements in Oregon, Arkansas and Michigan. However, Marley and the Pharmacy are still responsible for the actions undertaken on their behalf.

8. On October 5, 2017, the Maine Board of Pharmacy entered a Consent Order suspending the Pharmacy's permit in Maine for 90 days. Marley signed the Consent Order for the Pharmacy and testified he was aware that the Consent Order was entered. Nevertheless, the Pharmacy, under Marley's supervision, violated this Consent Order by unlawfully shipping ten (10) prescriptions into the State of Maine during the period of the Pharmacy's suspension.

9. Between September 1, 2016 and October 27, 2017, the Pharmacy (under Marley's supervision) unlawfully operated in the State of Texas without a pharmacist-manager who was licensed as a pharmacist in Texas.

10. Between June 28, 2017 and November 21, 2017, the Pharmacy was disciplined by the States of Alabama, Idaho, Louisiana, Maryland, Oklahoma and Texas. In addition, on August 30, 2017, the Pharmacy's employee, R.Ph. Robert Brent Clevenger, was disciplined by the State of Oklahoma. The Pharmacy, under Marley's supervision, did not disclose that disciplinary action to other states in which it was permitted until its next renewal application in each of those states. The Pharmacy, and Marley as its pharmacist-manager, therefore violated the laws of the following states requiring that those states be notified of discipline within a certain number of days following the disciplinary action: Alaska (30 days after both Permit and

Clevenger discipline), Colorado (30 days after Permit discipline), Connecticut (10 business days after Permit discipline), Georgia (five business days after Permit discipline), Illinois (60 days after both Permit and Clevenger discipline), Iowa (30 days after Permit discipline), Maine (10 days after Permit discipline), New Hampshire (30 days after Permit discipline), Oklahoma (10 days after Permit discipline), Pennsylvania (30 days after Permit discipline) and Tennessee (30 days after Permit and Clevenger discipline).

11. The Board incorporates by reference the following orders:

a. The Maryland Board of Pharmacy Pre-Charge Consent Order of June 28, 2017;

b. The Idaho Board of Pharmacy Stipulation and Consent Order of August 1, 2017;

c. The Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order of August 30, 2017;

d. The Maine Board of Pharmacy Consent Agreement of October 5, 2017;

e. The Texas Board of Pharmacy Agreed Board Order of November 7, 2017;

f. The Louisiana Board of Pharmacy Consent Agreement of November 15, 2017;

g. The Alabama Board of Pharmacy Consent Order of November 30, 2017;

h. The California Board of Pharmacy Citation and Fine of January 18, 2018;

i. The Maine Board of Pharmacy Consent Agreement of March 28, 2018; and

j. The New Hampshire Board of Pharmacy Notice of Violation of January 7, 2019;

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes. The statutes and rules that are at issue include, but are not limited to, N.C. Gen. Stat. §§ 90-85.38(a)(4), (6) and (7), 90-85.40(b) and (f) and 106-122(5); 21 NCAC 46 .1601(a) and (b), 46 .1804(a) and 46 .2501; Ala. Code §§ 20-2-51, 20-2-213, 34-23-30; 34-23-31 and 34-23-33; Ala. Admin. Code rr. 420-7-2-.12, 680-X-2-.07, 680-X-2-.12, 680-X-2-.22 and 680-X-3-.01; Alaska Stat. § 08.80.261; Alaska Admin. Code tit. 12, § 52.991; Ariz. Rev. Stat. §§ 32-1901.01, 32-1927.02, 32-1927.03, 32-1929, 32-1961, 32-1965, 36-2522 and 36-2608; Ariz. Admin. Code §§ R4-23-502, R4-23-601 and R4-23-607; Ark. Code Ann. §§ 17-92-311, 17-92-401, 17-92-404 and 17-92-407; 070-00-002 Ark. Code R. § 02-04-0002; 070-00-004 Ark. Code R. §§ 04-00-0009, 04-00-0010, 04-00-0011 and 04-04-0001; Cal. Bus. & Prof. Code §§ 4051, 4110, 4112, 4113, 4120, 4156, 4301, 4302, 4303, 4340 and 17500; Cal. Health & Safety Code §§ 11165 and 11352.1; Cal. Code Regs. tit. 16, §§ 1709.1 and 1766; Colo. Rev. Stat. §§ 12-42.5-112, 12-42.5-116, 12-42.5-123, 12-42.5-126 and 12-42.5-130; Colo. Code Regs. §§ 719-1:1.00.00, 719-1:7.00.00 and 719-1:9.00.00; Conn. Gen. Stat. § 20-627(b)(8); D.C. Code §§ 47-2885.03 and 47-2885.10; D.C. Mun. Regs. tit. 22-B, § 1903; Ga. Code Ann. §§ 16-13-30, 16-13-35, 16-13-37, 16-13-59, 16-13-64, 26-4-40, 26-4-60, 24-4-80, 24-4-110, 26-4-112, 26-4-113 and 26-4-114.1; Ga. Comp. R. & Regs. 480-5-.03, 480-6-.02, 480-10-.02, 480-20-.01 and 480-48.02; Haw. Rev. Stat. §§ 461-11, 461-15 and 461-21; Haw. Code R. §§ 16-95-18 and

16-95-110; Idaho Code §§ 54-1721, 54-1726, 54-1729, 54-1732 and 54-1758; Idaho Admin. Code rr. 27.01.02.020, 27.01.02.030 and 27.01.02.050; 225 Ill. Comp. Stat. §§ 85/5, 85/15, 85/16a and 85/30; Ill. Admin. Code tit. 68, §§ 1330.30, 1330.40, 1330.550 and 1330.660; Iowa Code § 155A.13A; Iowa Admin. Code r. 657-19.10(155A); Ky. Rev. Stat. §§ 315.030, 315.035, 315.0351 and 315.121; 201 Ky. Admin. Regs. 2:205; La. Stat. Ann. §§ 37:1201, 37:1221, 37:1232 and 37:1241; La. Admin. Code tit. 46, part LIII, §§ 1101, 1105, 1115 and 2301-2309; Me. Rev. Stat. Ann. tit. 32, §§ 13731, 13742-a, 13751, 13752, 13753 and 13754; 02-392-8 Me. Code R. §§ 6 and 8; 02-392-11 Me. Code R. §§ 3 and 4; 02-392-13 Me. Code R. § 3; 02-392-30 Me. Code R. § 1; 02-392-31 Me. Code R. § 2; Md. Code Ann. Health-Gen. § 21-2A-03; Md. Code Ann. Health Occ. §§ 12-307, 12-313, 12-401, 12-403, 12-409, 12-703 and 12-704; Md. Code Ann. Crim. Law §§ 5-301, 5-307, 5-602 and 5-701; Md. Code Regs. 10.19.03.03, 10.19.03.07, 10.34.10.01, 10.34.10.09, 10.34.37.04 and 10.47.07.03; Mich. Compl. Laws Ann. §§ 333.17711, 333.17741, 333.17748 and 333.1776; Mi. Admin. Code r. 338.477; Minn. Comp. Laws Ann. §§ 151.071, 151.18, 151.19 and 151.34; Minn. R. 6800.0110, 6800.0300, 6800.2250 and 6800.2400; Miss. Code Ann. §§ 73-21-97, 73-21-105 and 73-21-106; 30-20 Miss. Code R. §§ 3001:V, 3001:VI, 3001:VII and 3001:IX; Mont. Code Ann. §§ 37-7-321-to-323 and 37-7-703; Mont. Admin. R. 24.174.1001, 24.174.1003 and 24.174.2301; Neb. Rev. Stat. §§ 71-2407 and 71-2408; 172 Neb. Admin. Code §§ 128-007, 128-009 and 128-016; 175 Neb. Admin. Code §§ 8-003, 8-005 and 08-008; N.H. Rev. Stat. Ann. § 318:29; N.H. Code Admin R. Ph. 904.01; N.M. Stat. Ann. §§ 61-11-14, 61-11-15 and 61-11-20; N.M. Code R. §§ 16.19.6.24 and 16.19.27.7.B; Okla. Stat. tit. 59, §§ 353.17, 353.18, 353.24 and 353.26; Okla. Admin. Code §§ 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4.1, 535:15-3-4.2, 535:15-3-9, 535:25-7-3 and 535:25-9-3; Or. Rev. Stat. §§ 689.305, 689.335 and 689.405; Or.

Admin. R. 855-006-0020; 855-019-0200, 855-019-0300, 855-019-0310, 855-041-1010, 855-041-1060 and 855-041-1095; 63 Pa. Cons. Stat. §§ 390-4.1, 390-5 and 390-8; 73 Pa. Cons. Stat. §§ 201-2 and 201-3; 49 Pa. Code §§ 27.18 and 27.71; Tenn. Code Ann. §§ 39-17-417, 53-10-304, 53-10-305, 53-11-302, 63-10-210 and 63-10-306; Tenn. Comp. R. & Regs. 1140-01-.02, 1140-01-.08, 1140-01-.11, 1140-02-.01, 1140-03-.02, 1140-03-.03 and 1140-11-.05; Utah Code Ann. §§ 58-17b-302, 58-17b-501, 58-17b-502 and 58-17b-618; Utah Admin. Code r. 156-17b-502 and 156-17b-603; Vt. Stat. Ann. tit. 26, §§ 2041, 2061 and 2064; 20 4 Vt. Code R. §§ 1400:1.11, 1400:6.1, 1400:6.2, 1400:7.5, 1400:16.8 and 1400:20.2; W. Va. Code §§ 30-5-2, 30-5-22, 30-5-23, 30-5-24 and 30-5-31; W. Va. Code R. §§ 15-1-14. 15-1-19, 15-1-20, 15-6-3 and 15-6-6 to -8; Wyo. Stat. Ann. § 33-24-152; 059.0001 4 Wyo. Code R. § 2; and 059.0001 19 Wyo. Code R. § 11.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on his license under North Carolina General Statutes § 90-85.38(a)(4), (6) and (7).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The license of Respondent David Marley (License No. 12343) is hereby SUSPENDED for a period of ONE (1) YEAR AND TWO (2) WEEKS, to be served as follows:

   a. Two (2) weeks of the suspension must be served as an active suspension. These weeks shall be served on fourteen consecutive days between a Monday at 12:01 a.m. and the second following Sunday at 11:59 p.m.,

commencing within 30 days of the date that the Board accepts this Order, with Respondent to notify the Executive Director in writing and return his wallet card and original license in advance of service of the suspension.

b. The remaining one (1) year of the suspension shall be stayed for two (2) years from the date that the Board adopts this Order, upon the following conditions:

i. For a period of one (1) year from the date that the Board adopts this Order, Respondent shall not serve as pharmacist-manager, pharmacist-in-charge or equivalent position with respect to any pharmacy permit granted by this Board or any other jurisdiction.

(A) With respect to the North Carolina pharmacy permit of Marley Drug, Inc.: Within 3 days after this Consent Order is accepted by the Board, Respondent shall resign as pharmacist-manager of Marley Drug, Inc. and a replacement pharmacist-manager shall sign the permit indicating his or her service as pharmacist-manager, and that permit shall be received in the office of the Board. Respondent shall not serve as pharmacist-manager of any pharmacy permitted by this Board (including but not limited to Marley Drug, Inc.) for this one-year period.

(B) With respect to any pharmacy permits in other jurisdictions: If Respondent is serving as pharmacist-manager, pharmacist-in-charge or equivalent position in

any jurisdiction at the time of this Order, within three (3) days of the date that this Order is accepted by the Board, he shall provide written notice to any jurisdiction where he serves in any such position that he is immediately withdrawing from that position. A copy of that communication shall contemporaneously be provided to the Executive Director of this Board.

ii. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs (including, but not limited to, laws of the State of North Carolina and all other jurisdictions). Respondent specifically shall not dispense any drug, device or medical equipment that is shipped, mailed or delivered in any manner into any other jurisdiction without all required permits, registration and licenses;

iii. Respondent shall violate no rules and regulations of the Board or any other Board of Pharmacy;

iv. Respondent shall comply with all terms of this Order and any order of any other jurisdiction to which he is a party;

v. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives as well as the board of any other jurisdiction (and its agents) in any investigation or inspection; and

vi. Respondent shall advise the Board promptly in writing of any change of address or change in practice status.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

This the 19th day of March, 2019.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

David Marley, the holder of license number 12343, has full knowledge that he has the right to a formal hearing, at which he would have the right to be represented at his expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, he certifies that he has read the foregoing Consent Order and that he voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should he violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that he has the right to have counsel of his choice review and advise him with respect to his rights and this Consent Order, and represents that he enters this Consent Order after consultation with his counsel or after knowingly and voluntarily choosing not to consult with counsel.

ACCEPTED AND CONSENTED TO BY:

DAVID MARLEY (License No. 12343)

Date 3/14/2019

Witnessed:

Elizabeth Marley

[print name] Elizabeth Marley

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

April 16, 2019

David Marley, Pharmacist
5008 Peters Creek Pkwy
Winston Salem, NC 27127

DUPLICATE COPY
VIA FIRST CLASS MAIL
DATE 4/16/19

RE: License Number: 0202-212699
Case Number: 194911

Dear Mr. Marley:

Pursuant to Virginia Code § 54.1-2409, you are hereby given notice that your license to practice pharmacy in the Commonwealth of Virginia has been mandatorily suspended by the enclosed Order entered April 12, 2019. You are hereby advised that you may not practice pharmacy or hold yourself out as a licensed pharmacist unless and until the Board of Pharmacy has notified you in writing that your license has been reinstated. Please return your license to Caroline Juran, Executive Director of the Virginia Board of Pharmacy ("Board"), at the above address, immediately upon receipt of this letter.

You may apply to the Board for reinstatement of your license, and you shall be entitled to a formal administrative hearing not later than the next regular meeting of the Board after the expiration of 60 days from the Board's receipt of your reinstatement application. The reinstatement of your license shall require the affirmative vote of three-fourths of the members of the Board present at the hearing. The reinstatement application can be found at www.dhp.virginia.gov/Pharmacy.

If you have any questions about this matter, you can contact me at (804) 367-4474 or anne.joseph@dhp.virginia.gov.

Sincerely,

Anne Joseph

Anne Joseph, Deputy Director
Administrative Proceedings Division

cc: Caroline D. Juran, RPh, DPh, Executive Director, Virginia Board of Pharmacy
Enclosures

BEFORE THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

IN RE: **DAVID MARLEY, Pharmacist**
License Number: 0202-212699
Case Number: 194911

ORDER OF MANDATORY SUSPENSION

In accordance with Virginia Code § 54.1-2409, I, David E. Brown, D.C., Director of the Virginia Department of Health Professions, received and acted upon evidence that the North Carolina Board of Pharmacy entered a Consent Order suspending the license of David Marley, Pharmacist, to practice pharmacy in the State of North Carolina. A copy of the Consent Order is attached hereto as Commonwealth's Exhibit 1.

WHEREUPON, by the authority vested in the Director of the Department of Health Professions pursuant to Virginia Code § 54.1-2409, it is hereby ORDERED that the license of David Marley, Pharmacist, to practice pharmacy in the Commonwealth of Virginia is hereby SUSPENDED.

Upon entry of this Order, the license of David Marley, Pharmacist, will be recorded as suspended and no longer current and valid. Should Mr. Marley seek reinstatement of his license pursuant to Virginia Code § 54.1-2409, he shall be responsible for any fees that may be required for the reinstatement of the license prior to issuance of the license to resume practice.

Pursuant to Virginia Code § 2.2-4023 and § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection or copying on request.

David E. Brown, D.C., Director
Virginia Department of Health Professions

ENTERED:
4/12/19

CERTIFICATION OF DUPLICATE RECORDS

I, David E. Brown, D.C., Director of the Department of Health Professions, hereby certify that the attached Consent Order entered March 19, 2019, regarding David Marley, Pharmacist, is a true copy of the records received from the North Carolina Board of Pharmacy.

David E. Brown, D.C.

4/12/19
Date



BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: DAVID MARLEY (License No. 12343)	CONSENT ORDER

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for February 18, 2019 and, after appropriate notice, was heard on that day by Board Member Gene Minton at the office of the Board. Respondent David Marley (hereinafter "Respondent" or "Marley") was present and represented by counsel Crystal Carlisle. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that he waives his right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by his consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent David Marley is, and was at all relevant times referred to herein, the holder of License No. 12343 and the pharmacist-manager at Marley Drug, Inc., located at 5008 Peters Creek Parkway, Winston-Salem, North Carolina (Permit No. 27127) ("the Pharmacy"). Marley is, and was at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. Between December 18, 2013 and April 3, 2018, pharmacists at the Pharmacy, acting under the supervision of Marley as pharmacist-manager, unlawfully dispensed and shipped prescriptions into Alabama, Arizona, Arkansas, California, Colorado, the District of Columbia, Georgia, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Utah, Vermont, West Virginia and Wyoming at times when the Pharmacy did not have a permit in those states. Marley himself was the dispensing pharmacist on approximately twelve percent of these prescriptions.

4. Included among these prescriptions, between December 8, 2014 and March 8, 2017, were 33 controlled substance prescriptions that were unlawfully dispensed and shipped into Alabama (eleven schedule IV prescriptions), Arizona (five schedule III and IV prescriptions), California (ten schedule IV prescriptions), Georgia (one schedule IV prescription), Maryland (three schedule IV prescriptions), and Tennessee (two schedule III and IV prescriptions) under the supervision of Marley. These controlled substances were dispensed at times when the Pharmacy did not have a permit in those states and was not registered to dispense controlled substances into those states. Marley and the Pharmacy also did not report to those states' controlled substance prescription monitoring programs, as required by law. Marley himself was the dispensing pharmacist on five of these prescriptions unlawfully dispensed and

shipped into Alabama (one schedule IV prescription), Arizona (two schedule IV prescriptions) and California (two schedule IV prescriptions).

5. Marley testified that he had actual knowledge that the Pharmacy did not hold a permit in these states when the drugs were unlawfully dispensed and shipped, except for two states (Alabama and Maine) where he testified that, at least at certain times, he believed that the Pharmacy had a permit when its permit had actually lapsed. However, the Board finds that it was unreasonable for Marley to believe that the Pharmacy had a permit in Alabama or Maine at any point when the Pharmacy did not have a permit, because he was legally responsible for assuring that the Pharmacy had a current permit before shipping, he did not have a current permit from those states in his possession, and publicly available information would have revealed that the Pharmacy did not have an active permit in those states at those times. Moreover, on January 9, 2018, Marley received notification from the Maine Board that (the Board finds) did or should have informed him that the Pharmacy's Maine permit had not been renewed for 2018, but Marley nevertheless continued to ship into Maine until the permit was actually renewed on April 4, 2018.

6. As a mitigating factor as to shipments after December 14, 2016, on that date, the Pharmacy and Marley implemented remedial measures to attempt to ensure that prescriptions were not shipped into Arizona, Arkansas, California, the District of Columbia, Idaho, Louisiana, Maryland, Michigan, Montana, Nebraska, Oklahoma, Oregon and West Virginia until permits were secured. These measures did dramatically reduce the number of shipments over the prior time when the Pharmacy and Marley intended to ship without permits, but the Pharmacy still did make a relatively small number of unlawful shipments despite these efforts.

7. Between March 2016 and July 2017, the Pharmacy, and Marley as its pharmacist-manager, regularly and unlawfully held the Pharmacy out in radio advertising as a permitted pharmacy in certain states at times when, in fact, it was not permitted to operate as a pharmacy. These violations are as follows:

a. In March 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the Commonwealth of Pennsylvania by advertising on 63 occasions on a radio station in Pittsburgh;

b. Between July and September 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Illinois by advertising on 53 occasions on radio stations in Chicago;

c. Between July and December 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of California by advertising on 707 occasions on radio stations in Los Angeles, Sacramento and San Francisco;

d. During November and December 2016, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Louisiana by advertising on 200 occasions on radio stations in New Orleans;

e. During December 2016 and January 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Oregon by advertising on 170 occasions on a radio station in Portland;

f. Between February and July 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Alabama by advertising on 79 occasions on radio stations in Gadsden and Mobile;

g. Between March and June 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Arkansas by advertising on 79 occasions on a radio station in Fort Smith; and

h. In June 2017, Marley and the Pharmacy unlawfully held the Pharmacy out as permitted to dispense in the State of Michigan by advertising on 36 occasions on a radio station in Grand Rapids.

All advertisements run on and before December 14, 2016 were intentionally placed by Marley and the Pharmacy in states in which the Pharmacy was not permitted. However, as a mitigating

factor, the Board finds that – after December 14, 2016 – Marley Drug had instructed its advertising agency not to run advertising in certain states at the times of certain advertisements, but the advertising was run in violation of these instructions. This mitigating factor applies only to eighteen (18) of the advertisements in California and eighteen (18) of the advertisements in Louisiana on December 15 and 16, 2016; thirty-six (36) of the advertisements in Alabama from July 3 to 7, 2017; and all of the advertisements in Oregon, Arkansas and Michigan. However, Marley and the Pharmacy are still responsible for the actions undertaken on their behalf.

8. On October 5, 2017, the Maine Board of Pharmacy entered a Consent Order suspending the Pharmacy's permit in Maine for 90 days. Marley signed the Consent Order for the Pharmacy and testified he was aware that the Consent Order was entered. Nevertheless, the Pharmacy, under Marley's supervision, violated this Consent Order by unlawfully shipping ten (10) prescriptions into the State of Maine during the period of the Pharmacy's suspension.

9. Between September 1, 2016 and October 27, 2017, the Pharmacy (under Marley's supervision) unlawfully operated in the State of Texas without a pharmacist-manager who was licensed as a pharmacist in Texas.

10. Between June 28, 2017 and November 21, 2017, the Pharmacy was disciplined by the States of Alabama, Idaho, Louisiana, Maryland, Oklahoma and Texas. In addition, on August 30, 2017, the Pharmacy's employee, R.Ph. Robert Brent Clevenger, was disciplined by the State of Oklahoma. The Pharmacy, under Marley's supervision, did not disclose that disciplinary action to other states in which it was permitted until its next renewal application in each of those states. The Pharmacy, and Marley as its pharmacist-manager, therefore violated the laws of the following states requiring that those states be notified of discipline within a certain number of days following the disciplinary action: Alaska (30 days after both Permit and

Clevenger discipline), Colorado (30 days after Permit discipline), Connecticut (10 business days after Permit discipline), Georgia (five business days after Permit discipline), Illinois (60 days after both Permit and Clevenger discipline), Iowa (30 days after Permit discipline), Maine (10 days after Permit discipline), New Hampshire (30 days after Permit discipline), Oklahoma (10 days after Permit discipline), Pennsylvania (30 days after Permit discipline) and Tennessee (30 days after Permit and Clevenger discipline).

11. The Board incorporates by reference the following orders:

a. The Maryland Board of Pharmacy Pre-Charge Consent Order of June 28, 2017;

b. The Idaho Board of Pharmacy Stipulation and Consent Order of August 1, 2017;

c. The Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order of August 30, 2017;

d. The Maine Board of Pharmacy Consent Agreement of October 5, 2017;

e. The Texas Board of Pharmacy Agreed Board Order of November 7, 2017;

f. The Louisiana Board of Pharmacy Consent Agreement of November 15, 2017;

g. The Alabama Board of Pharmacy Consent Order of November 30, 2017;

h. The California Board of Pharmacy Citation and Fine of January 18, 2018;

i. The Maine Board of Pharmacy Consent Agreement of March 28, 2018; and

j. The New Hampshire Board of Pharmacy Notice of Violation of January 7, 2019.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes. The statutes and rules that are at issue include, but are not limited to, N.C. Gen. Stat. §§ 90-85.38(a)(4), (6) and (7), 90-85.40(b) and (f) and 106-122(5); 21 NCAC 46 .1601(a) and (b), 46 .1804(a) and 46 .2501; Ala. Code §§ 20-2-51, 20-2-213, 34-23-30, 34-23-31 and 34-23-33; Ala. Admin. Code rr. 420-7-2-.12, 680-X-2-.07, 680-X-2-.12, 680-X-2-.22 and 680-X-3-.01; Alaska Stat. § 08.80.261; Alaska Admin. Code tit. 12, § 52.991; Ariz. Rev. Stat. §§ 32-1901.01, 32-1927.02, 32-1927.03, 32-1929, 32-1961, 32-1965, 36-2522 and 36-2608; Ariz. Admin. Code §§ R4-23-502, R4-23-601 and R4-23-607; Ark. Code Ann. §§ 17-92-311, 17-92-401, 17-92-404 and 17-92-407; 070-00-002 Ark. Code R. § 02-04-0002; 070-00-004 Ark. Code R. §§ 04-00-0009, 04-00-0010, 04-00-0011 and 04-04-0001; Cal. Bus. & Prof. Code §§ 4051, 4110, 4112, 4113, 4120, 4156, 4301, 4302, 4303, 4340 and 17500; Cal. Health & Safety Code §§ 11165 and 11352.1; Cal. Code Regs. tit. 16, §§ 1709.1 and 1766; Colo. Rev. Stat. §§ 12-42.5-112, 12-42.5-116, 12-42.5-123, 12-42.5-126 and 12-42.5-130; Colo. Code Regs. §§ 719-1:1.00.00, 719-1:7.00.00 and 719-1:9.00.00; Conn. Gen. Stat. § 20-627(b)(8); D.C. Code §§ 47-2885.03 and 47-2885.10; D.C. Mun. Regs. tit. 22-B, § 1903; Ga. Code Ann. §§ 16-13-30, 16-13-35, 16-13-37, 16-13-59, 16-13-64, 26-4-40, 26-4-60, 24-4-80, 24-4-110, 26-4-112, 26-4-113 and 26-4-114.1; Ga. Comp. R. & Regs. 480-5-.03, 480-6-.02, 480-10-.02, 480-20-.01 and 480-48.02; Haw. Rev. Stat. §§ 461-11, 461-15 and 461-21; Haw. Code R. §§ 16-95-18 and

16-95-110; Idaho Code §§ 54-1721, 54-1726, 54-1729, 54-1732 and 54-1758; Idaho Admin. Code rr. 27.01.02.020, 27.01.02.030 and 27.01.02.050; 225 Ill. Comp. Stat. §§ 85/5, 85/15, 85/16a and 85/30; Ill. Admin. Code tit. 68, §§ 1330.30, 1330.40, 1330.550 and 1330.660; Iowa Code § 155A.13A; Iowa Admin. Code r. 657-19.10(155A); Ky. Rev. Stat. §§ 315.030, 315.035, 315.0351 and 315.121; 201 Ky. Admin. Regs. 2:205; La. Stat. Ann. §§ 37:1201, 37:1221, 37:1232 and 37:1241; La. Admin. Code tit. 46, part LIII, §§ 1101, 1105, 1115 and 2301-2309; Me. Rev. Stat. Ann. tit. 32, §§ 13731, 13742-a, 13751, 13752, 13753 and 13754; 02-392-8 Me. Code R. §§ 6 and 8; 02-392-11 Me. Code R. §§ 3 and 4; 02-392-13 Me. Code R. § 3; 02-392-30 Me. Code R. § 1; 02-392-31 Me. Code R. § 2; Md. Code Ann. Health-Gen. § 21-2A-03; Md. Code Ann. Health Occ. §§ 12-307, 12-313, 12-401, 12-403, 12-409, 12-703 and 12-704; Md. Code Ann. Crim. Law §§ 5-301, 5-307, 5-602 and 5-701; Md. Code Regs. 10.19.03.03, 10.19.03.07, 10.34.10.01, 10.34.10.09, 10.34.37.04 and 10.47.07.03; Mich. Compl. Laws Ann. §§ 333.17711, 333.17741, 333.17748 and 333.1776; Mi. Admin. Code r. 338.477; Minn. Comp. Laws Ann. §§ 151.071, 151.18, 151.19 and 151.34; Minn. R. 6800.0110, 6800.0300, 6800.2250 and 6800.2400; Miss. Code Ann. §§ 73-21-97, 73-21-105 and 73-21-106; 30-20 Miss. Code R. §§ 3001:V, 3001:VI, 3001:VII and 3001:IX; Mont. Code Ann. §§ 37-7-321-to-323 and 37-7-703; Mont. Admin. R. 24.174.1001, 24.174.1003 and 24.174.2301; Neb. Rev. Stat. §§ 71-2407 and 71-2408; 172 Neb. Admin. Code §§ 128-007, 128-009 and 128-016; 175 Neb. Admin. Code §§ 8-003, 8-005 and 08-008; N.H. Rev. Stat. Ann. § 318:29; N.H. Code Admin R. Ph. 904.01; N.M. Stat. Ann. §§ 61-11-14, 61-11-15 and 61-11-20; N.M. Code R. §§ 16.19.6.24 and 16.19.27.7.B; Okla. Stat. tit. 59, §§ 353.17, 353.18, 353.24 and 353.26; Okla. Admin. Code §§ 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4.1, 535:15-3-4.2, 535:15-3-9, 535:25-7-3 and 535:25-9-3; Or. Rev. Stat. §§ 689.305, 689.335 and 689.405; Or.

Admin. R. 855-006-0020; 855-019-0200, 855-019-0300, 855-019-0310, 855-041-1010, 855-041-1060 and 855-041-1095; 63 Pa. Cons. Stat. §§ 390-4.1, 390-5 and 390-8; 73 Pa. Cons. Stat. §§ 201-2 and 201-3; 49 Pa. Code §§ 27.18 and 27.71; Tenn. Code Ann. §§ 39-17-417, 53-10-304, 53-10-305, 53-11-302, 63-10-210 and 63-10-306; Tenn. Comp. R. & Regs. 1140-01-.02, 1140-01-.08, 1140-01-.11, 1140-02-.01, 1140-03-.02, 1140-03-.03 and 1140-11-.05; Utah Code Ann. §§ 58-17b-302, 58-17b-501, 58-17b-502 and 58-17b-618; Utah Admin. Code r. 156-17b-502 and 156-17b-603; Vt. Stat. Ann. tit. 26, §§ 2041, 2061 and 2064; 20 4 Vt. Code R. §§ 1400:1.11, 1400:6.1, 1400:6.2, 1400:7.5, 1400:16.8 and 1400:20.2; W. Va. Code §§ 30-5-2, 30-5-22, 30-5-23, 30-5-24 and 30-5-31; W. Va. Code R. §§ 15-1-14, 15-1-19, 15-1-20, 15-6-3 and 15-6-6 to -8; Wyo. Stat. Ann. § 33-24-152; 059.0001 4 Wyo. Code R. § 2; and 059.0001 19 Wyo. Code R. § 11.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on his license under North Carolina General Statutes § 90-85.38(a)(4), (6) and (7).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The license of Respondent David Marley (License No. 12343) is hereby SUSPENDED for a period of ONE (1) YEAR AND TWO (2) WEEKS, to be served as follows:

   a. Two (2) weeks of the suspension must be served as an active suspension. These weeks shall be served on fourteen consecutive days between a Monday at 12:01 a.m. and the second following Sunday at 11:59 p.m.,

commencing within 30 days of the date that the Board accepts this Order, with Respondent to notify the Executive Director in writing and return his wallet card and original license in advance of service of the suspension.

b. The remaining one (1) year of the suspension shall be stayed for two (2) years from the date that the Board adopts this Order, upon the following conditions:

i. For a period of one (1) year from the date that the Board adopts this Order, Respondent shall not serve as pharmacist-manager, pharmacist-in-charge or equivalent position with respect to any pharmacy permit granted by this Board or any other jurisdiction.

(A) With respect to the North Carolina pharmacy permit of Marley Drug, Inc.: Within 3 days after this Consent Order is accepted by the Board, Respondent shall resign as pharmacist-manager of Marley Drug, Inc. and a replacement pharmacist-manager shall sign the permit indicating his or her service as pharmacist-manager, and that permit shall be received in the office of the Board. Respondent shall not serve as pharmacist-manager of any pharmacy permitted by this Board (including but not limited to Marley Drug, Inc.) for this one-year period.

(B) With respect to any pharmacy permits in other jurisdictions: If Respondent is serving as pharmacist-manager, pharmacist-in-charge or equivalent position in

any jurisdiction at the time of this Order, within three (3) days of the date that this Order is accepted by the Board, he shall provide written notice to any jurisdiction where he serves in any such position that he is immediately withdrawing from that position. A copy of that communication shall contemporaneously be provided to the Executive Director of this Board.

ii. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs (including, but not limited to, laws of the State of North Carolina and all other jurisdictions). Respondent specifically shall not dispense any drug, device or medical equipment that is shipped, mailed or delivered in any manner into any other jurisdiction without all required permits, registration and licenses;

iii. Respondent shall violate no rules and regulations of the Board or any other Board of Pharmacy;

iv. Respondent shall comply with all terms of this Order and any order of any other jurisdiction to which he is a party;

v. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives as well as the board of any other jurisdiction (and its agents) in any investigation or inspection; and

vi. Respondent shall advise the Board promptly in writing of any change of address or change in practice status.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

This the 19th day of March, 2019.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

David Marley, the holder of license number 12343, has full knowledge that he has the right to a formal hearing, at which he would have the right to be represented at his expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, he certifies that he has read the foregoing Consent Order and that he voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should he violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that he has the right to have counsel of his choice review and advise him with respect to his rights and this Consent Order, and represents that he enters this Consent Order after consultation with his counsel or after knowingly and voluntarily choosing not to consult with counsel.

ACCEPTED AND CONSENTED TO BY:

DAVID MARLEY (License No. 12343)

Date 3/14/2019

Witnessed:

Elizabeth Marley

[print name] Elizabeth Marley

Code of Virginia
Title 54.1. Professions and Occupations
Chapter 24. General Provisions

§ 54.1-2409. Mandatory suspension or revocation; reinstatement; hearing for reinstatement.

A. Upon receipt of documentation by any court or government agency that a person licensed, certified, or registered by a board within the Department of Health Professions has had his license, certificate, or registration to practice the same profession or occupation revoked or suspended for reasons other than nonrenewal or accepted for surrender in lieu of disciplinary action in another jurisdiction and has not had his license, certificate, or registration to so practice reinstated within that jurisdiction, or has been convicted of a felony or has been adjudged incapacitated, the Director of the Department shall immediately suspend, without a hearing, the license, certificate, or registration of any person so disciplined, convicted or adjudged. The Director shall notify such person or his legal guardian, conservator, trustee, committee, or other representative of the suspension in writing to his address on record with the Department. Such notice shall include a copy of the documentation from such court or agency, certified by the Director as the documentation received from such court or agency. Such person shall not have the right to practice within this Commonwealth until his license, certificate, or registration has been reinstated by the Board.

B. The clerk of any court in which a conviction of a felony or an adjudication of incapacity is made, who has knowledge that a person licensed, certified, or registered by a board within the Department has been convicted or found incapacitated, shall have a duty to report these findings promptly to the Director.

C. When a conviction has not become final, the Director may decline to suspend the license, certificate, or registration until the conviction becomes final if there is a likelihood of injury or damage to the public if the person's services are not available.

D. Any person whose license, certificate, or registration has been suspended as provided in this section may apply to the board for reinstatement of his license, certificate, or registration. Such person shall be entitled to a hearing not later than the next regular meeting of the board after the expiration of 60 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify in his behalf. The Board may consider other information concerning possible violations of Virginia law at such hearing, if reasonable notice is given to such person of the information.

The reinstatement of the applicant's license, certificate, or registration shall require the affirmative vote of three-fourths of the members of the board at the hearing. The board may order such reinstatement without further examination of the applicant, or reinstate the license, certificate, or registration upon such terms and conditions as it deems appropriate.

E. Pursuant to the authority of the Board of Nursing provided in Chapter 30 (§ 54.1-3000 et seq.) of this title, the provisions of this section shall apply, mutatis mutandis, to persons holding a multistate licensure privilege to practice nursing.

1993, c. 991; 1997, c. 801; 2002, c. 455; 2004, c. 49; 2006, c. 367; 2010, c. 414; 2014, c. 76.

§ 54.1-2409.1. Criminal penalties for practicing certain professions and occupations without appropriate license.

Any person who, without holding a current valid license, issued by a regulatory board pursuant to this title (i) performs an invasive procedure for which a license is required; (ii) administers, prescribes, sells, distributes, or dispenses a controlled drug; or (iii) practices a profession or occupation after having his license to do so suspended or revoked shall be guilty of a Class 6 felony.

(1994, c. 722.)

Discipline Against License.

Date	Case #	Action
Jun 28 '17	PI-17-181	Maryland Board of Pharmacy Pre-Charge Consent Order ***NCBOP notified MDBOP Marley Drug had mailed prescriptions to Maryland patients prior to receiving permit.*** ***Action: Fine***
Aug 1 '17	BOP 17-061	Idaho board of Pharmacy Stipulation and Consent Order ***NCBOP notified IDBOP Marley Drug had mailed prescriptions to Idaho patients prior to receiving permit.*** ***Action: Fine***
Aug 30'17	1466	Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order ***NCBOP notified OKBOP Marley Drug had mailed prescriptions to Oklahoma patients prior to receiving permit and awaiting PIC licensure.*** ***Action: Fine***
Oct 5 '17	2017-PHA-13348	Maine Board of Pharmacy Consent Agreement ***NCBOP notified MEBOP Marley Drug had mailed prescriptions to Maine patients prior to receiving permit.*** ***Action: 90-day suspension, fine***
Nov 7 '17	K-17-034	Texas Board of Pharmacy Agreed Board Order ***NCBOP notified TXBOP Marley Drug had mailed prescriptions to Texas patients prior to receiving permit and awaiting PIC licensure.*** ***Action: Fine***
Nov 15 '17	17-0236	Louisiana Board of Pharmacy Consent Agreement ***NCBOP notified LABOP Marley Drug had mailed prescriptions to Louisiana patients prior to receiving permit and awaiting PIC licensure.*** ***Action: Fine***
Nov 30 '17	17-L-0073	Alabama Board of Pharmacy Consent Order ***NCBOP notified ALBOP Marley Drug had mailed prescriptions to Alabama patients prior to receiving permit and awaiting PIC licensure.*** ***Action: Fine***
Jan 18 '18	CI 2016 73000	California Board of Pharmacy Citation and Fine ***NCBOP notified CABOP Marley Drug had mailed prescriptions to California patients prior to receiving permit.*** ***Action: Fine***

EXTENDED SUPPLY MARLEY DRUG GENERIC DRUG PROGRAM

marleydrug.com
1.800.286.6781

NC licensed pharmacy, permit number 8320. All drugs are FDA approved, and purchased from state/federally licensed wholesalers.

PIEDMONT BUSINESS ETHICS AWARD
2013 WINNER

BBB ACCREDITED BUSINESS

2017 WINNER BEST PHARMACY JOURNAL READERS CHOICE

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

MARLEY DRUG
Generics you can afford, delivered to your door.



Mar 28 '18	2018-PHA-13930	Maine Board of Pharmacy Consent Agreement ***Marley Drug had failed to report discipline on renewal application*** ***Action: Reprimand, Fine***
Mar 4 '19		New Hampshire Board of Pharmacy Notice of Apparent Liability ***Marley Drug had failed to report discipline on renewal application*** ***Action: Fine***
Mar 19 '19		North Carolina Board of Pharmacy Consent Order ***NCBOP disciplined Marley Drug for shipping and advertising in several states prior to receiving permits and PIC licensures.*** ***Action: 30-day suspension stayed for 2 years***
Mar '19	2019-0029	Georgia Board of Pharmacy Consent Order ***NCBOP notified GABOP Marley Drug had mailed prescriptions to Georgia patients prior to receiving permit.*** ***Action: Fine***
Mar '19	18-54-012130	Pennsylvania Board of Pharmacy Consent Agreement and Order ***PABOP disciplined Marley Drug because of Alabama order*** ***Action: reprimand and fine***
Apr 15 '19	194916	Virginia Board of Pharmacy Order of Mandatory Suspension ***VABOP suspended Marley Drug because of NCBOP order. However, see VA order below*******
Apr 23 19	18-0393A	Kentucky Board of Pharmacy Agreed Order ***NCBOP notified KYBOP Marley Drug had mailed prescriptions to Kentucky patients prior to receiving permit.*** ***Action: Fine***
Apr 26 '19		New Jersey Board of Pharmacy Certification ***NCBOP notified NJBOP Marley Drug had mailed prescriptions to New Jersey patients prior to receiving permit.*** ***Action: Fine***
May 10 '19	2019-PHA-15281	Maine Board of Pharmacy Consent Order ***Order resulting from dispensing prescriptions to Maine patients while license was not active or on probation.*** ***Action: Reprimand, probation, fine***
Jul 18 '19	2019-0089	Oregon Board of Pharmacy Consent Order ***NCBOP notified ORBOP Marley Drug had mailed prescriptions to Oregon patients prior to receiving permit and PIC licensure.*** ***Action: Fine***

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

MARLEY DRUG™
Generics you can afford, delivered to your door.

marleydrug.com
1.800.286.6781

NC licensed pharmacy, permit number 8320. All drugs are FDA approved, and purchased from state/federally licensed wholesalers.

PIEDMONT BUSINESS ETHICS AWARD
2013 WINNER

BBB ACCREDITED BUSINESS

2017 WINNER BEST PHARMACY JOURNAL READERS CHOICE

Aug '19	L-19-015	Texas Board of Pharmacy Reprimand ***Texas issued a letter of reprimand for the various state discipline received through self-reporting*** ***Action: Reprimand***
Aug 22 '19	195988	Virginia Board of Pharmacy Consent Order ***Virginia offered an order that matched the stipulations in NCBOP consent order.*** ***Action: Reinstated permit.***
Aug 23 '19	2018-086	New Mexico Board of Pharmacy Settlement Agreement ***NCBOP notified NMBOP Marley Drug had mailed prescriptions to New Mexico patients prior to receiving permit.*** ***Action: Fine***
Aug 26 '19	2019-01-04	West Virginia Agreement and Order ***NCBOP notified GABOP Marley Drug had mailed prescriptions to Georgia patients prior to receiving permit.*** ***Action: Fine***
Jan 23 '20	2019-94-L	Hawaii Board of Pharmacy Settlement Agreement Fine/discipline imposed after review of discipline ***Hawaii issued a fine for the various state discipline received through self-reporting*** ***Action: Fine***

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

MARLEY DRUG™
Generics you can afford, delivered to your door.



marleydrug.com
1.800.286.6781

NC licensed pharmacy, permit number 8320. All drugs are FDA approved, and purchased from state/federally licensed wholesalers







Date	Case #	Action
Jun 28 '17	PI-17-181	Maryland Board of Pharmacy Pre-Charge Consent Order
Aug 1 '17	BOP 17-061	Idaho board of Pharmacy Stipulation and Consent Order
Aug 30'17	1466	Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order
Oct 5 '17	2017-PHA-13348	Maine Board of Pharmacy Consent Agreement
Nov 7 '17	K-17-034	Texas Board of Pharmacy Agreed Board Order
Nov 15 '17	17-0236	Louisiana Board of Pharmacy Consent Agreement
Nov 30 '17	17-L-0073	Alabama Board of Pharmacy Consent Order
Jan 18 '18	CI 2016 73000	California Board of Pharmacy Citation and Fine
Mar 28 '18	2018-PHA-13930	Maine Board of Pharmacy Consent Agreement
Jan 7 '19		New Hampshire Board of Pharmacy Notice of Violation
Mar 4 '19		New Hampshire Board of Pharmacy Notice of Apparent Liability
Mar 19 '19		North Carolina Board of Pharmacy Consent Order
Mar '19	2019-0029	Georgia Board of Pharmacy Consent Order
Mar '19	18-54-012130	Pennsylvania Board of Pharmacy Consent Agreement and Order
Apr 15 '19	194916	Virginia Board of Pharmacy Order of Mandatory Suspension
Apr 23 '19	18-0393A	Kentucky Board of Pharmacy Agreed Order
Apr 26 '19		New Jersey Board of Pharmacy Certification
May 10 '19	2019-PHA-15281	Maine Board of Pharmacy Consent Order
July 18 '19	2019-0089	Oregon Board of Pharmacy Consent Order
Aug '19	L-19-015	Texas Board of Pharmacy Reprimand
Aug 22 '19	195988	Virginia Board of Pharmacy Consent Order
Aug 23 '19	2018-086	New Mexico Board of Pharmacy Settlement Agreement
Aug 26 '19	2019-01-04	West Virginia Consent Agreement and Order
Jan 23 '20	2019-94-L	Hawaii Board of Pharmacy Settlement Agreement

February 3, 2020

5008 Peters Creek Parkway • Winston-Salem, NC 27127
Phone: 336.771.7672 • Fax: 336.771.9921 • marleydrug@bellsouth.net

MARLEY DRUG™
Generics you can afford, delivered to your door.

IN THE MATTER OF	*	**BEFORE THE**
MARLEY DRUG, INC.	*	**MARYLAND STATE**
PERMIT NO. P07484	*	**BOARD OF PHARMACY**
	*	

* * * * * * * * * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") received credible information indicating that Marley Drug, Inc., a pharmacy located and licensed in North Carolina, had dispensed prescription drugs to patients in Maryland prior to obtaining a non-resident pharmacy permit from the Board.

In lieu of instituting formal proceedings against Marley Drug, Inc., in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Marley Drug, Inc. have agreed to resolve this matter as set forth in this Pre-Charge Consent Order.

FINDINGS OF FACT

1. Marley Drug, Inc., is a pharmacy located and licensed in Winston Salem, North Carolina under Permit Number 08320.
2. Marley Drug, Inc.'s, pharmacy permit in North Carolina is active and in good standing.
3. On or about February 6, 2017, the Board received credible information from the North Carolina Board of Pharmacy that Marley Drug, Inc., had dispensed prescription drugs to patients in Maryland without a Maryland pharmacy permit.
4. The Board further received documentation from the North Carolina Board of

Pharmacy indicating that Marley Drug, Inc., dispensed approximately 112 prescriptions to patients residing at various locations throughout Maryland.

5. Marley Drug, Inc., dispensed the above prescription drugs between November 2014 and December 2016, prior to obtaining a Maryland pharmacy permit.
6. Marley Drug, Inc., obtained a non-resident pharmacy permit from the Maryland Board on February 3, 2017, which will expire on May 31, 2018.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Marley Drug, Inc., is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-401, 12-403(e), 12-703, and 12-707(e).

ORDER

Based upon an affirmative vote of a majority of the Board under the authority of Md. Code Ann., Health Occ. § 12-101, *et seq.*, it this 18th day of June, 2017, hereby,

ORDERED that Marley Drug, Inc., Permit No. P07484, shall pay a FINE in the amount of $2,500.00, payable to the Maryland Board of Pharmacy within ninety (90) days of the date of this Order, and mailed to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, MD 21203-2051

NOTE: Please include the case number, PI-17-181, on your check or money order to insure proper assignment to this case; and be it further,

ORDERED that Marley Drug, Inc., shall comply with all laws and regulations governing the dispensing of prescription drugs and devices into the State of Maryland by non-resident pharmacies; and be it further,

ORDERED that in the event that Marley Drug, Inc., violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension, revocation, and fines, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-333.

6-28-17
Date

Deena Speights-Napata
Executive Director for:

Mitra Gavgani, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Marley Drug, Inc., submits to the foregoing Pre-Charge Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. Marley Drug, Inc., acknowledges the validity of this Pre-Charge Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Marley Drug, Inc., acknowledges that, by entering into this Pre-Charge Consent Order, Marley Drug, Inc., is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Marley Drug, Inc., acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Pre-Charge Consent Order.

5. Marley Drug, Inc., signs this Pre-Charge Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Marley Drug, Inc., fully understands the language, meaning, and effect of this Pre-Charge Consent Order.

6/21/17
Date

Name: DAVID MARLEY
Title: CEO

STATE OF North Carolina
COUNTY/CITY OF Forsyth:

I hereby certify that on this 21 day of June, 2017, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared David Marley, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Marley Drug, Inc.

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: 4-17-2018

Rebecca S Newman
Notary Public
My commission expires: 4-17-2018

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License and Registration of:	)	
	)	Case No. BOP 17-061
MARLEY DRUG, INC.	)	
Mail Service Pharmacy License No. 44839MS,	)	**STIPULATION AND CONSENT ORDER**
	)	
Respondent.	)	
	)	

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for the initiation of an administrative action against Marley Drug, Inc. ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent is a licensee of the Board and holds Mail Service Pharmacy License No. 44839MS for mail service pharmacy in the state of Idaho. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

//

//

B. STIPULATED FACTS

1. Respondent is a drug supplier with its principal place of business in Winston-Salem, North Carolina. Respondent is a drug outlet as defined by Idaho Code § 54-1705(13) and a mail service pharmacy as defined by Idaho Code § 54-1705(22) and Idaho Board Rule 11 (IDAPA 27.01.01.011.02).

2. On February 6, 2017, the Board was advised by the North Carolina Board of Pharmacy that through a review of Respondent's dispensing records, it had discovered that Respondent had been shipping prescription medications to Idaho patients.

3. The documentation provided to the Board by the North Carolina Board of Pharmacy showed 19 instances of medications shipped to Idaho residents between May 2015 and December 2016.

4. Idaho Code § 54-1729(1), § 54-1729(2)(g) and and Idaho Board Rule 60 (IDAPA 27.01.01.060) require any mail service pharmacy providing drug products to Idaho residents to obtain and maintain a mail service pharmacy license in the state of Idaho. At the time the documented medications were shipped to the Idaho residents, Respondent did not hold an Idaho mail service pharmacy license.

5. The Board advised Respondent by letter dated February 8, 2017, that it was operating in violation of Idaho law. Respondent has since applied for and obtained its Idaho mail service pharmacy license.

6. While Respondent's violations may have been unintentional, Respondent acknowledges its actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondent admits to violating the following statutes and rules:

a. Idaho Code § 54-1729(1), (2)(g) (all drug outlets doing business in or into Idaho shall submit an application for licensure in one of the following classifications . . . (2)(g) mail service pharmacy);

b. IDAPA 27.01.01.060 (a license is required for drug outlets doing business in or into Idaho);

c. Idaho Code § 54-1726(1)(f) (the Board may suspend, revoke or restrict the license of any person, upon one or more of the following grounds. . .being found by the Board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter);

d. IDAPA 27:01.01.501 (the Board may suspend, revoke or restrict the license of an individual on one or more of the grounds provided in Idaho Code § 54-1726);

e. Idaho Code § 54-1728(2) (the board may take any action against a nonresident licensee as it may take against a resident licensee); and

f. Idaho Code § 54-1728(1)(f) (upon finding grounds for discipline, the board may impose an administrative fine not to exceed $2,000, plus prosecution and administrative costs).

7. Respondent, in lieu of proceeding with a formal disciplinary hearing, hereby agrees the Board may enter a final order against its license as set forth in Section C below.

C. STIPULATED PENALTIES

1. As stated in section B(6)(f) above, the Board is authorized to assess fines of up to $2,000 for each of the 19 drug products shipped to Idaho residents while Respondent was unlicensed, totaling $38,000. In the interests of fairness and efficiency, the Board is willing to limit its sanctions to 20 percent of the authorized fines. Therefore, it is agreed that Respondent

shall pay a fine of Seven Thousand Six Hundred Dollars ($7,600) for the violation outlined above in Section B. This fine shall be due to the Board within 180 days of the date this Order is signed.

2. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional action being taken against Respondent's mail service pharmacy license.

3. All costs associated with Respondent's compliance with the terms of this Stipulation and Order shall be borne solely by Respondent.

D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and its attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on the administrative complaint, any allegations of non-compliance will be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be borne solely by Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. Respondent admits to the allegations stated above in Section B. Respondent understands these allegations constitute cause for disciplinary terms upon its license. Respondent agrees the Board has jurisdiction to proceed in this matter with its consent as indicated by signature on its behalf hereto.

2. Respondent has read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondent understands and acknowledges that by its terms it is waiving certain rights provided under Idaho law.

3. Respondent understands that it has, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on its own behalf; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. Respondent hereby freely and voluntarily waives these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

4. Respondent understands that in signing this Stipulation, it is enabling the Board to impose disciplinary terms upon its license as set forth in Section C without further process.

5. Respondent understands the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondent understands that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the aforementioned terms, and Respondent hereby agrees to the above Stipulation for settlement. If the Board approves this Stipulation subject to changes, and those changes are acceptable,

Respondent acknowledges the Stipulation will take effect, and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable or the Board rejects this Stipulation, this Stipulation will be of no effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing.

6. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation and Consent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise.

10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly-scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member signs the attached Order.

DATED this 22 day of June, 2017.

MARLEY DRUG, INC.

By: [signature] DAVID MARLEY

Its: President

Authorized Representative for Respondent

[The remainder of this page is intentionally blank.]

I concur in this stipulation and order and recommend that the Board adopt the same.

DATED this 27th day of June, 2017.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

CARL J. WITHROE
Deputy Attorney General

I also concur in this stipulation and order and recommend the Board adopt the same.

DATED this 29th day of June, 2017.

IDAHO BOARD OF PHARMACY

By: Alex J. Adams

Alex J. Adams, PharmD, MPH
Executive Director

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order, and it is hereby ordered that Respondent comply with said terms and conditions.

DATED this 1st day of August, 2017.

Nicole Chopski, PharmD
Board Chair

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

RECEIVED
AUG 04 2017
OK STATE BOARD OF PHARMACY

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Marley Drug (99-7152)	)	Case No. 1466
5008 Peters Creek Pkwy	)	
Winston-Salem, NC 27127; and	)	
Robert Brent Clevenger, DPh #17326, PIC	)	Case No. 1467
2116 McClintock Rd, Unit 222	)	
Charlotte, NC 28205	)	

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on August 30, 2017, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams, and Whitehead were present. President Whitehead presided. Brinda K. White, Assistant Attorney General, served as prosecutor for the Board. Respondents did not appear.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondents hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondents have been advised of their right to contest the allegations against them, to cross-examine witnesses, and to present witnesses and evidence in their own defense. Respondents hereby knowingly and voluntarily waive these rights. In addition, Respondents understand and acknowledge that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondents agree that neither the presentation of the Order to the Board nor the Board's

consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent, Marley Drug (99-7152), is a licensed, non-resident pharmacy in the State of Oklahoma located at 5008 Peters Creek Pkwy, Winston-Salem, NC. Respondent Robert Brent Clevenger, DPh #17326, is an Oklahoma licensed pharmacist. Respondent Clevenger works as the pharmacist-in-charge. Dave Marley is fifty per cent (50%) owner of Respondent Pharmacy.

2. On February 4, 2015, Respondent Pharmacy obtained its Oklahoma pharmacy license. Respondent Pharmacy did not have an Oklahoma licensed pharmacist-in-charge for its 2016 pharmacy renewal. The Board notified Respondent Pharmacy of the requirement of having an Oklahoma licensed pharmacist-in-charge. After Respondent Pharmacy failed to respond, Respondent Pharmacy's application and fee were returned and the license was cancelled on March 31, 2016.

3. On January 27, 2017, Respondent Clevenger was issued an Oklahoma pharmacist's license. On February 5, 2017, Respondent Pharmacy's license was reinstated after Respondent Pharmacy hired Respondent Clevenger as its pharmacist-in-charge.

4. On April 21, 2017, the Board was notified by the North Carolina Board of Pharmacy that Respondent Pharmacy had shipped prescriptions into Oklahoma during the time that it was not licensed. The Board requested a

copy of prescriptions that had been shipped into Oklahoma. From April 4, 2016 until December 12, 2016, when Respondent Pharmacy was not licensed by the Board, Respondents shipped a total of seventy-six (76) prescriptions into Oklahoma. Thirty-six (36) of these prescriptions were filled by Respondent Clevenger.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondents have admitted violating OAC 535:15-3-9(b)(1) by failing, as a non-resident pharmacy, to make application and receive an annual non-resident pharmacy license at a fee set by the Board, as set forth in Count I of the Complaint.

4. Respondents have admitted violating OAC 535:15-3-9(c)(2) by failing to follow Oklahoma pharmacy laws and regulations in the practice of pharmacy for the Oklahoma portion of the non-resident pharmacy's practice or operation. Specifically, the pharmacist manager (pharmacist-in-charge) and pharmacy owners(s), partners, and corporate officers(s) are responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering of prescriptions or prescription medications and devices to Oklahoma residents, as set forth in Count II of the Complaint.

5. Respondents have admitted violating 59 O.S. § 353.18(A)(1) by selling at retail, or offering for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and

drugs or accepting prescriptions for the same, without first procuring a license from the Board, as set forth in Count III of the Complaint.

6. Respondents have admitted violating OAC 535:25-7-3(a) by failing to conduct business at all times in conformity with all federal, state and municipal laws, as set forth in Count IV of the Complaint.

7. Pursuant to 59 O.S. §353.7(12), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

8. Based on the above Agreed Findings of Fact, Respondents are subject to disciplinary action pursuant to 59 O.S. §§ 353.7 and 353.26.

AGREED ORDER

1. Respondent, Marley Drug, holder of pharmacy license No. 99-7152, admits to guilt on all four (4) counts. Respondent, Robert Brent Clevenger, holder of pharmacist license No. 17326, admits to guilt on all four (4) counts.

2. Respondent Marley Drug is hereby fined One Thousand Nine Hundred Dollars ($1,900.00) per count for a total fine of Seven Thousand Six Hundred Dollars ($7600.00). Respondent, Robert Brent Clevenger, is hereby fined Two Hundred Twenty-Five Dollars ($225.00) per count for a total fine of Nine Hundred Dollars ($900.00). These fines are due August 30, 2017.

3. Failure of Respondents to abide by any of the terms of this Agreed Order could result in further disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

4. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

Kyle Whitehead, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 30th day of August, 2017.

CYNTHIA R. FAIN NOTARY PUBLIC # 00003042 EXP. 02/18/20 STATE OF OKLAHOMA

Cindy R Fain
Notary Public

My Commission Expires:

(SEAL)

I am a fifty percent (50%) owner of Marley Drug (99-7152), and, therefore, I am authorized to sign on behalf of Marley Drug (99-7152). I have read the above Agreed Findings of Fact, Conclusions of Law and Final Order. I understand that by its terms Marley Drug (99-7152) will be waiving certain rights accorded it under Oklahoma Law. I also understand that by its terms Marley Drug (99-7152) must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on it. On behalf of Marley Drug (99-7152), I agree to the above Agreed Order.

Dated this 1 **day of** August, **2017.**

Marley Drug (99-7152), Respondent

By: Dave Marley

State of North Carolina)
) ss.
County of Forsyth)

Subscribed and sworn before me on this the 1 day of August, 2017, by Dave Marley.

Rebecca S Newman
Notary Public

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: 4-17-2019

I have read the above Agreed Findings of Fact, Conclusions of Law and Final Order. I understand that by its terms I will be waiving certain rights accorded me under Oklahoma Law. I also understand that by its terms I must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on me. I agree to the above Agreed Order.

Dated this 1st **day of** August, **2017.**

Robert Brent Clevenger, DPh #17326
Respondent

State of North Carolina)
) ss.
County of Forsyth)

Subscribed and sworn before me on this the 1 day of August, 2017.

Notary Public

My Commission Expires:

(SEAL)

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: 11-19-2019

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MARLEY DRUG, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2017-PHA-13348	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Marley Drug, Inc. in the State of Maine. The parties to this Consent Agreement are: Marley Drug, Inc. ("Marley Drug"), the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. Marley Drug is licensed by the Board as a mail order pharmacy, license no. MO40001812, with a registered location of 5008 Peters Creek Parkway in Winston-Salem, North Carolina.
2. Between November 24, 2014, and December 12, 2016, Marley Drug filled and shipped 48 prescriptions to patients in Maine prior to being licensed as a mail order pharmacy in the State of Maine.
3. In 2017 Marley Drug applied to the Board to obtain a mail order pharmacy license.
4. On March 29, 2017, the Board granted Marley Drug a mail order pharmacy license.
5. On June 6, 2017, the Board received an email from the North Carolina Board of Pharmacy that provided evidence that Marley Drug had shipped prescriptions to Maine patients prior to March 29, 2017.

6. On June 20, 2017, Board Staff filed a complaint with the Board alleging that Marley Drug had practiced as a mail order pharmacy without having been licensed to do so.
7. The Board docketed this complaint as complaint no. 2017-PHA-13348.
8. On September 7, 2017, following a presentation of the complaint, the Board voted to offer Marley Drug this Consent Agreement in order to resolve Complaint No. 2017-PHA-13348.
9. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Cathy Neumann, Complaint Coordinator, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333-0035 by October 18, 2017, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

10. Marley Drug admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(4) for violating a governing law of the Board, specifically 32 M.R.S. § 13731(1), by repeatedly engaging in the practice of pharmacy without having been licensed to do so.
11. As DISCIPLINE for the violations admitted to in paragraph 10 above, Marley Drug agrees to accept the imposition of:
    a. A REPRIMAND;
    b. A 90-DAY LICENSE SUSPENSION, which suspension shall commence on the day of final execution by all the parties to this Consent Agreement; and
    c. A CIVIL PENALTY in the amount of twenty-four thousand dollars ($24,000.00). Payment of the civil penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Cathy Neumann,

Complaint Coordinator, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, within thirty (30) days of the execution of this Consent Agreement.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. Violation of any of the terms or conditions of this Consent Agreement by Marley Drug shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

14. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

15. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

16. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

17. The Board and Marley Drug agree that no further agency action will be initiated against Marley Drug's license by the Board based upon the specific violations admitted to herein, except or unless Marley Drug fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Marley Drug. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against Marley Drug.

18. Marley Drug acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

MARLEY DRUG, INC.

DATED: 9/21/17

BY: _____
Authorized Representative

DAVID MARLEY, CEO
Printed Name

DATED: 9/29/2017

_____
JOSEPH BRUNO, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 10/5/2017

_____
ANDREW L. BLACK
Assistant Attorney General

AGREED BOARD ORDER #K-17-034

RE: IN THE MATTER OF
MARLEY DRUG, INC.
(PHARMACY LICENSE #28974)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28974 issued to Marley Drug, Inc. (Respondent), 5008 Peters Creek Parkway, Winston-Salem, North Carolina 27127.

By letter dated October 27, 2017, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2017), in that allegedly:

COUNT

On or about September 1, 2016, through on or about October 27, 2017, Marley Drug, Inc., 5008 Peters Creek Parkway, Winston-Salem, North Carolina 27127, was engaged in the operation of a non-resident pharmacy in violation of Texas Pharmacy Board Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated October 27, 2017, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Dave Marley, Corporate President, Marley Drug, Inc., on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2017).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of November, 2017.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Dave Marley, Corporate President of
For and on behalf of Marley Drug, Inc.

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

MARLEY DRUG, INC.

LOUISIANA PHARMACY PERMIT NO. 7512 **Case No. 17-0236**

****

CONSENT AGREEMENT

WHEREAS, **MARLEY DRUG, INC.** (hereinafter referred to as "Respondent"), Louisiana Pharmacy Permit No. 7512, 5008 Peters Creek Pkwy, Winston Salem, North Carolina 27127, dispensed 344 prescriptions into Louisiana without a Louisiana non-resident pharmacy permit.

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B): No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

LAC Title 46: LIII §2305. Out-of-State Pharmacy Permit Requirements

A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.

To facilitate the submission of this Consent Agreement, Respondent agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **A Letter of Warning is issued to Louisiana Pharmacy Permit No. 7512; and**
2. **Respondent is ordered to pay a fine of $15,000.00 and to reimburse the Board $250.00 for administrative costs, with total payment due the Board of $15,250.00, to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter and waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting.

However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: 1376640201

Medicare Provider Number (if in the possession of one): N/A

I, DAVID MARLEY, authorized to act on behalf of and acting on behalf of **MARLEY DRUG, INC.,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

SIGNED, AGREED TO AND ENTERED ON THIS 25 DAY OF September, 2017.

MARLEY DRUG, INC.
Louisiana Pharmacy Permit NO. 7512

BY: Authorized Representative

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on November 15, **2017**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron
President and Hearing Officer for the Board

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
MARLEY DRUG, INC.	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy	)	**CASE NO: 17-L-0073**
Permit Number: 114311	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Marley Drug, Inc. which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) § 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Marley Drug, Inc. has violated the provisions of law based upon the conduct set out in all Counts of the Statement.

2. Marley Drug, Inc. shall pay an administrative fine in the amount of Thirty Thousand Dollars ($30,000.00) within ninety (90) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Marley Drug, Inc. expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and

§40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Marley Drug, Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Marley Drug, Inc. hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Marley Drug, Inc. acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Marley Drug, Inc.'s permit, including, but not limited to revocation.

6. Marley Drug, Inc. acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Marley Drug, Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 21 of November, 2017.

MARLEY DRUG, INC.

BY: _____

ITS: CEO

11/30/2017

DONE this the _____ of _____, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
MARLEY DRUG, INC.	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy	)	**CASE NO: 17-L-0073**
Permit Number: 114311	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Marley Drug, Inc.**
5008 Peters Creek Parkway
Winston-Salem, North Carolina 27127

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on February 13, 2018 at 1:00 p.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Marley Drug, Inc. (Marley) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Marley has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(7) in that you violated Code of Alabama (1975), § 34-23-30 and/or 31 by dispensing medications into the State of Alabama without a current or valid permit to do so during 2015, 2016 and/or up to and including July, 2017.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the Pre-Charge Consent Order entered by the Maryland State Board of Pharmacy on June 28, 2017 attached hereto as Exhibit "A" and/or dispensing prescription drugs to patients in Maryland without a permit to do so as set out in the referenced Order.

COUNT FOUR

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Three above.

COUNT FIVE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the Agreed Findings of Fact, Conclusions of Law and Final Order entered by the Oklahoma State Board of Pharmacy on August 30, 2017 attached hereto as Exhibit "B" and/or you dispensing medication to residents of Oklahoma without a license to do so as set out in the referenced Order.

COUNT SIX

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count Five above.

COUNT SEVEN

Violating Code of Alabama (1975), § 34-23-33(6) based upon any or all of the

allegations of the preceding Counts.

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT EIGHT

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 26th day of October, 2017.

ALABAMA STATE BOARD OF PHARMACY

Susan Alverson

By: Susan Alverson
Secretary

EXHIBIT A

IN THE MATTER OF	*	BEFORE THE
MARLEY DRUG, INC.	*	MARYLAND STATE
PERMIT NO. P07484	*	BOARD OF PHARMACY
	*	

* * * * * * * * * * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") received credible information indicating that Marley Drug, Inc., a pharmacy located and licensed in North Carolina, had dispensed prescription drugs to patients in Maryland prior to obtaining a non-resident pharmacy permit from the Board.

In lieu of instituting formal proceedings against Marley Drug, Inc., in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq*., the Board and Marley Drug, Inc. have agreed to resolve this matter as set forth in this Pre-Charge Consent Order.

FINDINGS OF FACT

1. Marley Drug, Inc., is a pharmacy located and licensed in Winston Salem, North Carolina under Permit Number 08320.
2. Marley Drug, Inc.'s, pharmacy permit in North Carolina is active and in good standing.
3. On or about February 6, 2017, the Board received credible information from the North Carolina Board of Pharmacy that Marley Drug, Inc., had dispensed prescription drugs to patients in Maryland without a Maryland pharmacy permit.
4. The Board further received documentation from the North Carolina Board of

Pharmacy indicating that Marley Drug, Inc, dispensed approximately 112 prescriptions to patients residing at various locations throughout Maryland.

5. Marley Drug, Inc., dispensed the above prescription drugs between November 2014 and December 2016, prior to obtaining a Maryland pharmacy permit.
6. Marley Drug, Inc., obtained a non-resident pharmacy permit from the Maryland Board on February 3, 2017, which will expire on May 31, 2018.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Marley Drug, Inc., is subject to discipline in accordance with Md. Code Ann., Health Occ §§ 12-401, 12-403(e), 12-703, and 12-707(e).

ORDER

Based upon an affirmative vote of a majority of the Board under the authority of Md. Code Ann., Health Occ. § 12-101, *et seq.*, it this 28th day of June, 2017, hereby

ORDERED that Marley Drug, Inc., Permit No. P07484, shall pay a FINE in the amount of $2,500.00, payable to the Maryland Board of Pharmacy within ninety (90) days of the date of this Order, and mailed to

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, MD 21203-2051

NOTE: Please include the case number, P1-17-181, on your check or money order to insure proper assignment to this case and be it further,

ORDERED that Marley Drug, Inc., shall comply with all laws and regulations governing the dispensing of prescription drugs and devices into the State of Maryland by non-resident pharmacies; and be it further,

ORDERED that in the event that Marley Drug, Inc., violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension, revocation, and fines, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-333.

6-28-17
Date

Deena Speights-Napata
Executive Director for:

Mitra Gavgani, Pharm.D
Board President

CONSENT

1. By signing this Consent, Marley Drug, Inc., submits to the foregoing Pre-Charge Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. Marley Drug, Inc., acknowledges the validity of this Pre-Charge Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Marley Drug, Inc., acknowledges that, by entering into this Pre-Charge Consent Order, Marley Drug, Inc., is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Marley Drug, Inc., acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Pre-Charge Consent Order.

5. Marley Drug, Inc., signs this Pre-Charge Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Marley Drug, Inc., fully understands the language, meaning, and effect of this Pre-Charge Consent Order.

6/21/17
Date

Name: David Marley
Title: CEO

STATE OF North Carolina
COUNTY/CITY OF Forsyth

I hereby certify that on this 21 day of June 2017, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared David Marley, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Marley Drug, Inc.

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp. 4-17-2018

Rebecca S Newman
Notary Public
My commission expires: 4-17-2018

EXHIBIT B

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

RECEIVED
STATE BOARD OF PHARMACY

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Marley Drug (99-7152) 5008 Peters Creek Pkwy Winston-Salem, NC 27127; and	)	Case No. 1466
Robert Brent Clevenger, DPh #17326, PIC 2116 McClintock Rd, Unit 222 Charlotte, NC 28205	)	Case No. 1467

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on August 30, 2017, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams and Whitehead were present. President Whitehead presided. Brinda K. White, Assistant Attorney General, served as prosecutor for the Board. Respondents did not appear.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondents hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondents have been advised of their right to contest the allegations against them, to cross-examine witnesses, and to present witnesses and evidence in their own defense. Respondents hereby knowingly and voluntarily waive these rights. In addition, Respondents understand and acknowledge that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondents agree that neither the presentation of the Order to the Board nor the Board's

OCT 23 2017

consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent, Marley Drug (99-7152), is a licensed, non-resident pharmacy in the State of Oklahoma located at 5008 Peters Creek Pkwy, Winston-Salem, NC. Respondent Robert Brent Clevenger, DPh #17326, is an Oklahoma licensed pharmacist. Respondent Clevenger works as the pharmacist-in-charge Dave Marley is fifty per cent (50%) owner of Respondent Pharmacy.

2 On February 4, 2015, Respondent Pharmacy obtained its Oklahoma pharmacy license. Respondent Pharmacy did not have an Oklahoma licensed pharmacist-in-charge for its 2016 pharmacy renewal. The Board notified Respondent Pharmacy of the requirement of having an Oklahoma licensed pharmacist-in-charge. After Respondent Pharmacy failed to respond, Respondent Pharmacy's application and fee were returned and the license was cancelled on March 31, 2016.

3. On January 27, 2017, Respondent Clevenger was issued an Oklahoma pharmacist's license. On February 5, 2017 Respondent Pharmacy's license was reinstated after Respondent Pharmacy hired Respondent Clevenger as its pharmacist-in-charge.

4. On April 21, 2017, the Board was notified by the North Carolina Board of Pharmacy that Respondent Pharmacy had shipped prescriptions into Oklahoma during the time that it was not licensed. The Board requested a

copy of prescriptions that had been shipped into Oklahoma. From April 4, 2016 until December 12, 2016, when Respondent Pharmacy was not licensed by the Board, Respondents shipped a total of seventy-six (76) prescriptions into Oklahoma. Thirty-six (36) of these prescriptions were filled by Respondent Clevenger.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondents have admitted violating OAC 535:15-3-9(b)(1) by failing, as a non-resident pharmacy, to make application and receive an annual non-resident pharmacy license at a fee set by the Board, as set forth in Count I of the Complaint.

4. Respondents have admitted violating OAC 535:15-3-9(c)(2) by failing to follow Oklahoma pharmacy laws and regulations in the practice of pharmacy for the Oklahoma portion of the non-resident pharmacy's practice or operation. Specifically, the pharmacist manager (pharmacist-in-charge) and pharmacy owners(s) partners, and corporate officers(s) are responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering of prescriptions or prescription medications and devices to Oklahoma residents, as set forth in Count II of the Complaint.

5. Respondents have admitted violating 59 O.S. § 353.18(A)(1) by selling at retail, or offering for sale, dangerous drugs, medicines, chemicals or poisons for the treatment of disease, excluding agricultural chemicals and

drugs or accepting prescriptions for the same, without first procuring a license from the Board, as set forth in Count III of the Complaint.

6. Respondents have admitted violating OAC 535:25-7-3(a) by failing to conduct business at all times in conformity with all federal, state and municipal laws, as set forth in Count IV of the Complaint.

7. Pursuant to 59 O.S. §353.7(12), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules the Board has authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation to reprimand, place on probation or suspend or revoke the license of a licensee, to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs including, but not limited to, staff time, salary and travel expense witness fees and attorney fees.

8. Based on the above Agreed Findings of Fact Respondents are subject to disciplinary action pursuant to 59 O.S. §§ 353.7 and 353.26.

AGREED ORDER

1. Respondent, Marley Drug, holder of pharmacy license No. 99-7152, admits to guilt on all four (4) counts. Respondent, Robert Brent Clevenger, holder of pharmacist license No. 17326, admits to guilt on all four (4) counts.

2. Respondent Marley Drug is hereby fined One Thousand Nine Hundred Dollars ($1,900.00) per count for a total fine of Seven Thousand Six Hundred Dollars ($7600.00). Respondent, Robert Brent Clevenger, is hereby fined Two Hundred Twenty-Five Dollars ($225.00) per count for a total fine of Nine Hundred Dollars ($900.00). These fines are due August 30, 2017.

3. Failure of Respondents to abide by any of the terms of this Agreed Order could result in further disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

4. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

Kyle Whitehead, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss
County of Oklahoma)

Subscribed and sworn before me on this the 30th day of August 2017.

Notary Public

My Commission Expires:

(SEAL)

I am a fifty percent (50%) owner of Marley Drug (99-7152), and, therefore, I am authorized to sign on behalf of Marley Drug (99-7152). I have read the above Agreed Findings of Fact, Conclusions of Law and Final Order. I understand that by its terms Marley Drug (99-7152) will be waiving certain rights accorded it under Oklahoma Law. I also understand that by its terms Marley Drug (99-7152) must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on it. On behalf of Marley Drug (99-7152), I agree to the above Agreed Order.

Dated this 1 day of August, 2017.

Marley Drug (99-7152), Respondent

By: Dave Marley

State of North Carolina)
) ss
County of Forsyth)

Subscribed and sworn before me on this the 1 day of August 2017, 2017 by Dave Marley.

Rebecca S. Newman
Notary Public

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp. 6-17-2019

I have read the above Agreed Findings of Fact, Conclusions of Law and Final Order. I understand that by its terms I will be waiving certain rights accorded me under Oklahoma Law. I also understand that by its terms I must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on me. I agree to the above Agreed Order.

Dated this 15th day of August, 2017.

Robert Brent Clevenger, DPh #17326
Respondent

State of North Carolina)
) ss
County of Forsyth)

Subscribed and sworn before me on this the 1 day of August 2017
2017

Rebecca S. Newman
Notary Public

My Commission Expires

(SEAL)

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: [illegible] 2021

OCT 23 2017

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2016 73000	MARLEY DRUG INC, NRP 1940

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4112 subd. (a) & (b)	Nonresident pharmacy: registration required/All nonresident pharmacies shall register with the board...	$4,000.00
Bus. & Prof. Code § 4340	Unlawful Advertising by Nonresident Pharmacy Not Registered with Board	$1,000.00

CONDUCT:

Business and Professions Code 4112 (a) and (b) states in pertinent part any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy. A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. Marley Drug was not in compliance with this regulation. Specifically, between 3/7/2014 to 3/7/2017, Marley Drug (NRP 1940) located at 5008 Peters Creek Parkway in Winston-Salem, NC, shipped 1,443 prescriptions into California prior to becoming licensed with the State of California as a nonresident pharmacy. Marley Drug did not become licensed as a non-resident pharmacy until 3/8/2017. This was a violation of pharmacy law.

Business and Professions Code 4340 states in pertinent part it is unlawful for any nonresident pharmacy that is not registered pursuant to Section 4112 or for any person who is a resident of this state to advertise the pharmacy services of any pharmacy, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions. Marley Drug was not in compliance with this regulation. Specifically, a California resident heard an advertisement on AM radio 650 from Marley Drug (NRP 1940) located at 5008 Peters Creek Parkway in Winston-Salem, NC explaining they could provide Viagra prescriptions at a discounted rate. The resident contacted Marley Drug and received a response from Marley Drug by email on 10/25/2016 and 11/1/2016 providing a flyer advertising drug and shipping prices. Marley Drug did not become licensed as a nonresident pharmacy until 3/8/2017. This was a violation of pharmacy law.

CITATION ISSUED ON: January 16, 2018	TOTAL AMOUNT OF FINE(S): $5,000.00

PAYMENT OF FINE(S) DUE BY: February 15, 2018

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MARLEY DRUG, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2018-PHA-13930	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Marley Drug, Inc., doing business as "Marley Drug," for the renewal of its license to operate as a mail order pharmacy. The parties to this Consent Agreement are: Marley Drug, Inc. ("Marley Drug"), the Maine Board of Pharmacy ("the Board"), and the Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since March 24, 2016, Marley Drug has been licensed by the Board as a mail order pharmacy, license number MO40001812, located at 5008 Peters Creek Parkway in Winston Salem, North Carolina.
2. On October 5, 2017, Marley Drug entered into a consent agreement with the Board to resolve Case No. 2017-PHA-13348, pursuant to which consent agreement Marley Drug admitted to shipping 48 prescriptions to Maine patients prior to it becoming licensed by the Board as a mail order pharmacy in 2016.
3. On January 8, 2018, the Board received Marley Drug's online renewal application.

4. On this renewal application, Marley Drug answered "Yes" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

5. As required by the application, Marley Drug then reported to the Board the following discipline previously imposed by other states:

   a. June 28, 2017, Maryland, Pre-Charged Consent Order, in which Marley Drug admitted to shipping 112 prescriptions without having obtained a non-resident pharmacy permit;

   b. August 1, 2017, Idaho, Stipulation and Consent Order, Case No. BOP 17-061, in which Marley Drug admitted to shipping 19 prescriptions to Idaho without being licensed as a mail service pharmacy;

   c. August 30, 2017, Oklahoma, Agreed Findings of Fact, Conclusions of Law and Final Order, Case Nos. 1466 & 1467, in which Marley Drug admitted to shipping 76 prescriptions to Oklahoma without being licensed as a non-resident pharmacy;

   d. November 7, 2017, Texas, Agreed Board Order #K-17-034, in which Marley Drug admitted to operating a non-resident pharmacy that was not under the supervision of a pharmacist-in-charge who was licensed as a pharmacist in Texas;

   e. November 15, 2017, Louisiana, Consent Order, Case No. 17-0236, in which Marley Drug admitted to shipping 344 prescriptions without having obtained a non-resident pharmacy permit; and

   f. November 21, 2017, Alabama, Consent Order, Case No. 17-L-0073, in which Marley Drug admitted to shipping 31 prescriptions without proper registration.

6. Prior to January 8, 2018, however, Marley Drug had not reported to the Board the discipline that it disclosed on its license renewal application.

7. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report disciplinary action to the Board within 10 days of that action.

8. At its meeting on February 1, 2018, the Board reviewed the above information and voted to preliminarily deny Marley Drug's application for the renewal of its mail order pharmacy license. In lieu of the denial, the Board also voted to offer Marley Drug this Consent Agreement. Unless Marley Drug either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Complaint Coordinator, Maine Board of Pharmacy, 35 State House Station, Augusta, ME 04333, by **April 2, 2018** the preliminary denial of Marley Drug's application for the renewal of its mail order pharmacy license will become final.

COVENANTS

9. Marley Drug admits to the facts as stated above and admits that such conduct constitutes grounds for the refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken.

10. As discipline for the conduct admitted to in paragraph 9 above, Marley Drug agrees to accept the following DISCIPLINARY ACTION:

a. A REPRIMAND;

b. LICENSE PROBATION for a period of one year, which period shall commence on the effective date of this consent agreement and during which period Marley Drug's license shall be subject to the following conditions:

   i. Within 30 days of the effective date of this consent agreement Marley Drug shall provide to the Board a written statement attesting to the fact that all shareholders and the pharmacist in charge have read and understand Maine pharmacy laws and the Board's rules;

   ii. Marley Drug shall comply with all Maine pharmacy laws and Board rules; and

   iii. In the event of a failure to comply with the conditions of probation, Marley Drug shall be subject to the imposition of any suspended civil penalty and/or any suspended license suspension imposed by this Consent Agreement;

c. A CIVIL PENALTY in the amount of nine thousand dollars ($9,000.00), comprised of a $1,500.00 penalty for each of the six disciplinary actions that Marley Drug failed to report to the Board in a timely manner, with all but $3,000.00 suspended, the suspension of which penalty is conditioned on Marley Drug's successful completion of the one-year probation, and which payment of the non-suspended penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Complaint Coordinator, Maine Department of Professional and Financial Regulation, 35

State House Station, Augusta, Maine 04333, at the time the signed Consent Agreement is submitted; and

d. A LICENSE SUSPENSION for a period of five hundred forty (540) days all of which license suspension shall be suspended subject to Marley Drug's satisfactory completion of the one-year license probation.

11. Violation of any of the terms or conditions of this Consent Agreement by Marley Drug shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. Upon receipt of the signed Consent Agreement and the civil penalty payment, the Board will renew Marley Drug's license contingent upon it meeting all other eligibility criteria.

15. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

16. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

17. The Board and Marley Drug agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Marley Drug fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of

misconduct in the event that other allegations are brought against Marley Drug and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving Marley Drug. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Marley Drug.

18. Marley Drug acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 3/7/18

MARLEY DRUG, INC.
d/b/a Marley Drug

By: David Mosley

Title: CEO

DATED: 3/23/2018

JOSEPH BRUNO, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 3/28/2018

ANDREW L. BLACK
Assistant Attorney General

STATE OF NEW HAMPSHIRE
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION
DIVISION OF HEALTH PROFESSIONS
BOARD OF PHARMACY

121 South Fruit Street, Suite 401
Concord, NH 03301-2412
Phone 603-271-2350 • Fax 603-271-2856
www.oplc.nh.gov/pharmacy

OPLC
Peter Danles
Executive Director
Sheri Walsh Esq.
Director, Health Professions

Board of Pharmacy
Michael D. Bullek, R.Ph.
Administrator / Chief of Compliance
Jason R. Richard
Licensing Supervisor

January 7th, 2019

Marley Drug
C/O Dave Marley, CEO
5008 Peters Creek Parkway
Winston-Salem, NC 27127

CERTIFIED MAIL and FIRST CLASS MAIL

NOTICE OF VIOLATION

Dear Mr. Marley;

The Board has received information concerning discipline on Marley Drug's (respondent) Non-Resident Pharmacy license # NR 1075 from the following Boards of Pharmacy;

1. Alabama Board of Pharmacy. The date of the Alabama Board order, November 21st, 2017, was not reported to the New Hampshire Board of Pharmacy until November 26th 2018.
2. California Board of Pharmacy. The date of the California Board order, January 16th, 2018, was not reported to the New Hampshire Board of Pharmacy until November 26th, 2018.
3. Louisiana Board of Pharmacy. The date of the Louisiana Board order, September 25th, 2017, was not reported to the New Hampshire Board of Pharmacy until November 26th, 2018.
4. Maine Board of Pharmacy. The date of the Maine Board order, March 28th, 2018, was not reported to the New Hampshire Board of Pharmacy until November 26th, 2018.
5. Texas Board of Pharmacy. The date of the Texas Board order, November 7th, 2017, was not reported to the New Hampshire Board of Pharmacy until November 26th, 2018.

All changes to a New Hampshire license shall be reported to the Board pursuant to Ph 904.01.

Ph 904.01 Reporting Changes.

(a) The mail-order pharmacy to which a registration has been issued shall within 30-days of any change of information supplied in the original application, notify the board.

Under RSA 318:29 and RSA 318:55, the Board may impose civil penalties "not to exceed $5,000 per violation upon any person who willfully or repeatedly violates any provision of this chapter." It appears that by engaging in the conduct described above you may have violated RSA 318:29, I (b) and Ph 904.01.

The Board sees fit to use its discretion to propose an administrative fine of **$150.00** You have the following two options upon receipt of this Notice. First, you can waive the right to a hearing and pay the proposed fine. If you choose to do so, please pay the fine within thirty (30) days of receipt of this Notice and remit payment to Treasurer, State of New Hampshire. Second, you may request a hearing on the matter. If you do so, your request for a hearing must be received within thirty (30) days of receipt of this Notice. The Board will thereafter schedule a hearing.

If you have any questions, please don't hesitate to contact this office at (603)-271-2350.

Dated: January 7th, 2019

Michael D. Bullek, BSP, R. Ph
Administrator/Chief of Compliance
Authorized Representative of the
New Hampshire Board of Pharmacy

Date: 1/28/19

Signature:

~~Healthcare Specialty Transaction Services~~
MARSH DRUG, Inc.

Title: CEO.

*/ Board Member recused

State of New Hampshire
Board of Pharmacy
Concord, New Hampshire

In the Matter of:
Marley Drug
Registration No.: NR1075

NOTICE OF APPARENT LIABILITY

Pursuant to New Hampshire RSA 318:29; RSA 318:30; RSA 318:31; Pharmacy Administrative Rule ("Ph") 204; Ph 904 and Ph 402, the New Hampshire Board of Pharmacy ("Board") has the authority to investigate allegations of professional misconduct and, at any time, to dispose of such allegations by *Notice of Apparent Liability*, without commencing a disciplinary hearing. The Board also has the authority to assess and collect administrative fines against entities such as Marley Drug that are permitted by the Board and whose conduct is found to violate state or federal laws and/or the New Hampshire Pharmacy Board Administrative Rules. *See* RSA 318:29; and Ph 905.01 (a)(1).

As authorized to do so, the Board hereby issues a *Notice of Apparent Liability* to Marley Drug.

In support of the *Notice of Apparent Liability*, the Board sets forth the following facts:

1. On or about November 9th, 2018 Marley Drug applied for a license renewal of non-resident/mail order pharmacy # NR 1075.
2. On or about November 9th, 2018 Marley Drug answered the question during license renewal on line **"PH-NR Since your last renewal, has the license/registration of this pharmacy been subject to disciplinary action by**

any state or federal licensing/regulatory board/agency? " The question was answered **"NO".**

3. On or about November 9th, 2018 Marley Drug answered the question during license renewal on line **"PH NR Attestation- I attest that I have answered all questions truthfully, accurately and I hereby attest that if any information on this renewal application was submitted falsely or is misleading or a misrepresentation of the facts, I understand that such an act shall constitute cause for potential denial, revocation, or disciplinary actions of the license/registration that I am applying for in the State of New Hampshire."** The question was answered **"YES".**

4. On or about November 26th, 2018 a Memo was received from Marley Drug outlining disciplinary actions from 8 Boards of Pharmacy, Maryland, Idaho, Oklahoma, Maine, Texas, Louisiana, Alabama and California, for inclusion with license renewal.

5. Marley Drug neither admits nor denies the facts set forth above, but consents to the Board's authority to make findings against it as set forth above, and accepts the following sanction imposed by this *Notice of Apparent Liability*:

6. Based upon the violations of law set forth in paragraphs above, the Board hereby assesses Marley Drug an administrative fine in the amount of $2,000.00 dollars. The entire amount of the fine is to be paid within thirty (30) days of the issuance of this *Notice of Apparent Liability* by mailing or delivering a certified bank check or money order made payable to "Treasurer, State of New Hampshire" to the Board's office at 121 South Fruit Street, Concord, NH 03301.

7. Marley Drug agrees to pay the administrative fine as specified above within thirty (30) days of the issuance of the *Notice of Apparent Liability* or request that a public administrative hearing be scheduled by the Board. If a hearing is requested, the *Notice of Apparent Liability* shall be withdrawn and a *Notice of Hearing* shall be proposed for issuance by the Board. At such a hearing, the Board's disciplinary options shall not be limited to the assessment of a civil administrative penalty.

8. Except as provided herein, the payment of the assessed administrative fine shall bar the commencement of further action by the Board based upon the conduct described above. However, the Board may consider this conduct in the event that similar conduct is proven against Marley Drug. in the future.

BY ORDER OF THE BOARD/*

FOR THE RESPONDENT

Date: 3/4/19

(signature)

DAVID MARLEY

(print name)
Duly Authorized Representative of
Marley Drug

N.H. Board of Pharmacy
In the matter of Marley Drug
Notice of Apparent Liability

FOR THE NEW HAMPSHIRE BOARD OF PHARMACY*

Date: February 21st, 2019

Michael D. Bullek BSP R.Ph.
Authorized Representative of the
New Hampshire Board of Pharmacy

/* Board Member(s), recused:

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: MARLEY DRUG, INC. (Permit No. 8320)	)	**CONSENT ORDER**

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for February 18, 2019 and, after appropriate notice, was heard on that day by Board Member Gene Minton at the office of the Board. Respondent Marley Drug, Inc. (hereinafter "Respondent" or the "Pharmacy") was present through its pharmacist-manager David Marley and represented by counsel Crystal Carlisle. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by its consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent Marley Drug, Inc., located at 5008 Peters Creek Parkway, Winston-Salem, North Carolina, is, and was at all relevant times referred to herein, the holder of Permit No. 8320. The Pharmacy is, and was at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. Between December 18, 2013 and April 3, 2018, the Pharmacy unlawfully dispensed and shipped prescriptions into Alabama, Arizona, Arkansas, California, Colorado, the District of Columbia, Georgia, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Utah, Vermont, West Virginia and Wyoming at times when the Pharmacy did not have a permit in those states.

4. Included among these prescriptions, between December 8, 2014 and March 8, 2017, were 33 controlled substance prescriptions that were unlawfully dispensed and shipped into Alabama (eleven schedule IV prescriptions), Arizona (five schedule III and IV prescriptions), California (ten schedule IV prescriptions), Georgia (one schedule IV prescription), Maryland (three schedule IV prescriptions), and Tennessee (two schedule III and IV prescriptions). These controlled substances were dispensed at times when the Pharmacy did not have a permit in those states and was not registered to dispense controlled substances into those states. The Pharmacy also did not report to those states' controlled substance prescription monitoring programs, as required by law.

5. The Pharmacy's pharmacist-manager testified that he had actual knowledge that the Pharmacy did not hold a permit in these states when the drugs were unlawfully dispensed and shipped, except for two states (Alabama and Maine) where he testified that, at least at certain times, he believed that the Pharmacy had a permit when its permit had actually lapsed.

However, the Board finds that it was unreasonable for the pharmacist-manager to believe that the Pharmacy had a permit in Alabama or Maine at any point when the Pharmacy did not have a permit, because the Pharmacy did not have a current permit for those states in its possession and publicly available information would have revealed that the Pharmacy did not have an active permit in those states at those times. Moreover, on January 9, 2018, the Pharmacy received notification from the Maine Board that (the Board finds) did or should have informed it that its Maine permit had not been renewed for 2018, but the Pharmacy nevertheless continued to ship into Maine until the permit was actually renewed on April 4, 2018.

6. As a mitigating factor as to shipments after December 14, 2016, on that date, the Pharmacy implemented remedial measures to attempt to ensure that prescriptions were not shipped into Arizona, Arkansas, California, the District of Columbia, Idaho, Louisiana, Maryland, Michigan, Montana, Nebraska, Oklahoma, Oregon and West Virginia until permits were secured. These measures did dramatically reduce the number of shipments over the prior time when the Pharmacy intended to ship without permits, but the Pharmacy still did make a relatively small number of unlawful shipments despite these efforts.

7. Between March 2016 and July 2017, the Pharmacy regularly and unlawfully held itself out in radio advertising as a permitted pharmacy in certain states at times when, in fact, it was not permitted to operate as a pharmacy. These violations are as follows:

a. In March 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the Commonwealth of Pennsylvania by advertising on 63 occasions on a radio station in Pittsburgh;

b. Between July and September 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Illinois by advertising on 53 occasions on radio stations in Chicago;

c. Between July and December 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of California by advertising on

707 occasions on radio stations in Los Angeles, Sacramento and San Francisco;

d. During November and December 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Louisiana by advertising on 200 occasions on radio stations in New Orleans;

e. During December 2016 and January 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Oregon by advertising on 170 occasions on a radio station in Portland;

f. Between February and July 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Alabama by advertising on 79 occasions on radio stations in Gadsden and Mobile;

g. Between March and June 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Arkansas by advertising on 79 occasions on a radio station in Fort Smith; and

h. In June 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Michigan by advertising on 36 occasions on a radio station in Grand Rapids.

All advertisements run on and before December 14, 2016 were intentionally placed by the Pharmacy in states in which the Pharmacy was not permitted. However, as a mitigating factor, the Board finds that – after December 14, 2016 – the Pharmacy had instructed its advertising agency not to run advertising in certain states at the times of certain advertisements, but the advertising was run in violation of these instructions. This mitigating factor applies only to eighteen (18) of the advertisements in California and eighteen (18) of the advertisements in Louisiana on December 15 and 16, 2016; thirty-six (36) of the advertisements in Alabama from July 3 to 7, 2017; and all of the advertisements in Oregon, Arkansas and Michigan. However, the Pharmacy is still responsible for the actions undertaken on its behalf.

8. On October 5, 2017, the Maine Board of Pharmacy entered a Consent Order suspending the Pharmacy's permit in Maine for 90 days. The pharmacist-manager signed the Consent Order for the Pharmacy and testified he was aware that the Consent Order was entered.

Nevertheless, the Pharmacy violated this Consent Order by unlawfully shipping ten (10) prescriptions into the State of Maine during the period of the Pharmacy's suspension.

9. Between September 1, 2016 and October 27, 2017, the Pharmacy unlawfully operated in the State of Texas without a pharmacist-manager who was licensed as a pharmacist in Texas.

10. Between June 28, 2017 and November 21, 2017, the Pharmacy was disciplined by the States of Alabama, Idaho, Louisiana, Maryland, Oklahoma and Texas. In addition, on August 30, 2017, the Pharmacy's employee, R.Ph. Robert Brent Clevenger, was disciplined by the State of Oklahoma. The Pharmacy did not disclose that disciplinary action to other states in which it was permitted until its next renewal application in each of those states. The Pharmacy therefore violated the laws of the following states requiring that those states be notified of discipline within a certain number of days following the disciplinary action: Alaska (30 days after both Permit and Clevenger discipline), Colorado (30 days after Permit discipline), Connecticut (10 business days after Permit discipline), Georgia (five business days after Permit discipline), Illinois (60 days after both Permit and Clevenger discipline), Iowa (30 days after Permit discipline), Maine (10 days after Permit discipline), New Hampshire (30 days after Permit discipline), Oklahoma (10 days after Permit discipline), Pennsylvania (30 days after Permit discipline) and Tennessee (30 days after Permit and Clevenger discipline).

11. The Board incorporates by reference the following orders:

a. The Maryland Board of Pharmacy Pre-Charge Consent Order of June 28, 2017;

b. The Idaho Board of Pharmacy Stipulation and Consent Order of August 1, 2017;

c. The Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order of August 30, 2017;

d. The Maine Board of Pharmacy Consent Agreement of October 5, 2017;

e. The Texas Board of Pharmacy Agreed Board Order of November 7, 2017;

f. The Louisiana Board of Pharmacy Consent Agreement of November 15, 2017;

g. The Alabama Board of Pharmacy Consent Order of November 30, 2017;

h. The California Board of Pharmacy Citation and Fine of January 18, 2018;

i. The Maine Board of Pharmacy Consent Agreement of March 28, 2018; and

j. The New Hampshire Board of Pharmacy Notice of Violation of January 7, 2019.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes. The statutes and rules that are at issue include, but are not limited to, N.C. Gen. Stat. §§ 90-85.38(a)(4), (6) and (7) and (b), 90-85.40(b) and (f) and 106-122(5); 21 NCAC 46 .1601(a) and (b), 46 .1804(a) and 46 .2501; Ala. Code §§ 20-2-51, 20-2-213, 34-23-30, 34-23-31 and 34-23-33; Ala. Admin. Code rr. 420-7-2-.12, 680-X-2-.07, 680-X-2-.12, 680-X-2-.22 and 680-X-3-.01; Alaska Stat. § 08.80.261; Alaska Admin. Code tit. 12, § 52.991;

Ariz. Rev. Stat. §§ 32-1901.01, 32-1927.02, 32-1927.03, 32-1929, 32-1961, 32-1965, 36-2522 and 36-2608; Ariz. Admin. Code §§ R4-23-502, R4-23-601 and R4-23-607; Ark. Code Ann. §§ 17-92-311, 17-92-401, 17-92-404 and 17-92-407; 070-00-002 Ark. Code R. § 02-04-0002; 070-00-004 Ark. Code R. §§ 04-00-0009, 04-00-0010, 04-00-0011 and 04-04-0001; Cal. Bus. & Prof. Code §§ 4051, 4110, 4112, 4113, 4120, 4156, 4301, 4302, 4303, 4340 and 17500; Cal. Health & Safety Code §§ 11165 and 11352.1; Cal. Code Regs. tit. 16, §§ 1709.1 and 1766; Colo. Rev. Stat. §§ 12-42.5-112, 12-42.5-116, 12-42.5-123, 12-42.5-126 and 12-42.5-130; Colo. Code Regs. §§ 719-1:1.00.00, 719-1:7.00.00 and 719-1:9.00.00; Conn. Gen. Stat. § 20-627(b)(8); D.C. Code §§ 47-2885.03 and 47-2885.10; D.C. Mun. Regs. tit. 22-B, § 1903; Ga. Code Ann. §§ 16-13-30, 16-13-35, 16-13-37, 16-13-59, 16-13-64, 26-4-40, 26-4-60, 24-4-80, 24-4-110, 26-4-112, 26-4-113 and 26-4-114.1; Ga. Comp. R. & Regs. 480-5-.03, 480-6-.02, 480-10-.02, 480-20-.01 and 480-48.02; Haw. Rev. Stat. §§ 461-11, 461-15 and 461-21; Haw. Code R. §§ 16-95-18 and 16-95-110; Idaho Code §§ 54-1721, 54-1726, 54-1729, 54-1732 and 54-1758; Idaho Admin. Code rr. 27.01.02.020, 27.01.02.030 and 27.01.02.050; 225 Ill. Comp. Stat. §§ 85/5, 85/15, 85/16a and 85/30; Ill. Admin. Code tit. 68, §§ 1330.30, 1330.40, 1330.550 and 1330.660; Iowa Code § 155A.13A; Iowa Admin. Code r. 657-19.10(155A); Ky. Rev. Stat. §§ 315.030, 315.035, 315.0351 and 315.121; 201 Ky. Admin. Regs. 2:205; La. Stat. Ann. §§ 37:1201, 37:1221, 37:1232 and 37:1241; La. Admin. Code tit. 46, part LIII, §§ 1101, 1105, 1115 and 2301-2309; Me. Rev. Stat. Ann. tit. 32, §§ 13731, 13742-a, 13751, 13752, 13753 and 13754; 02-392-8 Me. Code R. §§ 6 and 8; 02-392-11 Me. Code R. §§ 3 and 4; 02-392-13 Me. Code R. § 3; 02-392-30 Me. Code R. § 1; 02-392-31 Me. Code R. § 2; Md. Code Ann. Health-Gen. § 21-2A-03; Md. Code Ann. Health Occ. §§ 12-307, 12-313, 12-401, 12-403, 12-409, 12-703 and 12-704; Md. Code Ann. Crim. Law §§ 5-301, 5-307, 5-602 and 5-701; Md.

Code Regs. 10.19.03.03, 10.19.03.07, 10.34.10.01, 10.34.10.09, 10.34.37.04 and 10.47.07.03; Mich. Compl. Laws Ann. §§ 333.17711, 333.17741, 333.17748 and 333.1776; Mi. Admin. Code r. 338.477; Minn. Comp. Laws Ann. §§ 151.071, 151.18, 151.19 and 151.34; Minn. R. 6800.0110, 6800.0300, 6800.2250 and 6800.2400; Miss. Code Ann. §§ 73-21-97, 73-21-105 and 73-21-106; 30-20 Miss. Code R. §§ 3001:V, 3001:VI, 3001:VII and 3001:IX; Mont. Code Ann. §§ 37-7-321-to-323 and 37-7-703; Mont. Admin. R. 24.174.1001, 24.174.1003 and 24.174.2301; Neb. Rev. Stat. §§ 71-2407 and 71-2408; 172 Neb. Admin. Code §§ 128-007, 128-009 and 128-016; 175 Neb. Admin. Code §§ 8-003, 8-005 and 08-008; N.H. Rev. Stat. Ann. § 318:29; N.H. Code Admin R. Ph. 904.01; N.M. Stat. Ann. §§ 61-11-14, 61-11-15 and 61-11-20; N.M. Code R. §§ 16.19.6.24 and 16.19.27.7.B; Okla. Stat. tit. 59, §§ 353.17, 353.18, 353.24 and 353.26; Okla. Admin. Code §§ 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4.1, 535:15-3-4.2, 535:15-3-9, 535:25-7-3 and 535:25-9-3; Or. Rev. Stat. §§ 689.305, 689.335 and 689.405; Or. Admin. R. 855-006-0020; 855-019-0200, 855-019-0300, 855-019-0310, 855-041-1010, 855-041-1060 and 855-041-1095; 63 Pa. Cons. Stat. §§ 390-4.1, 390-5 and 390-8; 73 Pa. Cons. Stat. §§ 201-2 and 201-3; 49 Pa. Code §§ 27.18 and 27.71; Tenn. Code Ann. §§ 39-17-417, 53-10-304, 53-10-305, 53-11-302, 63-10-210 and 63-10-306; Tenn. Comp. R. & Regs. 1140-01-.02, 1140-01-.08, 1140-01-.11, 1140-02-.01, 1140-03-.02, 1140-03-.03 and 1140-11-.05; Utah Code Ann. §§ 58-17b-302, 58-17b-501, 58-17b-502 and 58-17b-618; Utah Admin. Code r. 156-17b-502 and 156-17b-603; Vt. Stat. Ann. tit. 26, §§ 2041, 2061 and 2064; 20 4 Vt. Code R. §§ 1400:1.11, 1400:6.1, 1400:6.2, 1400:7.5, 1400:16.8 and 1400:20.2; W. Va. Code §§ 30-5-2, 30-5-22, 30-5-23, 30-5-24 and 30-5-31; W. Va. Code R. §§ 15-1-14, 15-1-19, 15-1-20, 15-6-3 and 15-6-6 to -8; Wyo. Stat. Ann. § 33-24-152; 059.0001 4 Wyo. Code R. § 2; and 059.0001 19 Wyo. Code R. § 11.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The permit of Respondent Marley Drug, Inc. (Permit No. 8320) is hereby SUSPENDED for a period of ONE (1) MONTH, all of which is stayed for two (2) years from the date that the Board adopts this Order, upon the following conditions

a. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs (including, but not limited to, laws of the State of North Carolina and all other jurisdictions). Respondent specifically shall not dispense any drug, device or medical equipment that is shipped, mailed or delivered in any manner into any other jurisdiction without all required permits, registration and licenses;

b. Respondent shall violate no rules and regulations of the Board or any other Board of Pharmacy;

c. Respondent shall comply with all terms of this Order and any order of any other jurisdiction to which it is a party; and

d. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives as well as the board of any other jurisdiction (and its agents) in any investigation or inspection.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

This the 19th day of March, 2019.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

Marley Drug, Inc., the holder of permit number 27127, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Consent Order, and represents that it enters this Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel. The undersigned certifies that its agent executing this Consent Order is duly authorized to accept the Consent Order on behalf of Marley Drug, Inc., and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

MARLEY DRUG, INC.
(Permit No. ~~27127~~) 8320

By: _____ Date 3/7/19
Chris Holler
(Printed Name)

Its: Pharmacy Manager
(Position)

NORTH CAROLINA
Forsyth COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day, and acknowledged the due execution of the foregoing document: Chris Holler

Date: 3-7-2019

Rebecca S. Newman
Notary Public
Rebecca S. Newman

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: 4-17-2023

My commission expires: 4-17-2023

****

REJECTED BY:

_____ Date_____
MARLEY DRUG, INC.
(Permit No. 8320)

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
MARLEY DRUG, INC,	)	**DOCKET NO.**
License No. PHNR000569,	)	
	)	
Respondent.	)	

GEORGIA STATE BOARD OF PHARMACY
MAR 29 2019
DOCKET NO. 2019-0029

CONSENT ORDER

By agreement of the Georgia State Board of Pharmacy ("Board") and Marley Drug, Inc., Respondent, the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. § 50-13-13(a)(4).

FINDINGS OF FACT

1.

Respondent has a non-resident professional license to practice pharmacy in the State of Georgia. This license was issued June 9, 2015, and expires June 30, 2019.

2.

On or about November 12, 2018, GDNA was notified by the North Carolina Board of Pharmacy that an investigation of Respondent yielded information that the pharmacy shipped medications into the State of Georgia without being properly licensed as a non-resident pharmacy. Specifically, Respondent shipped prescriptions into the State of Georgia from on or about April 1, 2015 to June 8, 2015, with a pending application, prior to being licensed as a non-resident pharmacy.

CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4 and T. 43, Ch. 1, the Georgia State Board of Pharmacy has authority to take action against the license of the Respondent.

Respondent agrees that the Board can impose disciplinary action against the license of the Respondent and waives any further conclusions of law with respect to this matter.

ORDER

The Georgia State Board of Pharmacy, having considered the particular facts and circumstances of this case, hereby orders, and the Respondent hereby agrees that the Respondent's license shall be disciplined as follows:

1.

The Respondent shall submit to the Board a fine in the amount of **$1,000.00**. Such fine shall be payable within ninety (90) days from the effective date of this Consent Order. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy. Payment shall be sent to the Board, c/o Executive Director, 2 Peachtree Street, N.W., 6th Floor, Atlanta, Georgia 30303. The Respondent's failure to pay such fine by the ninetieth day shall subject Respondent's license to further disciplinary action, including revocation.

2.

Approval of this Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning Respondent's conduct and shall not be construed as a waiver of any of the lawful rights possessed by the Board. This Consent Order shall not become effective until approved and docketed by the Board.

3.

Respondent acknowledges that he/she has read this Consent Order and understands its contents. Respondent understands that there is a right to a hearing in this matter, and Respondent freely, knowingly and voluntarily waives such right by

entering into this Consent Order. Respondent understands that this Consent Order will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Consent Order. Respondent further understands that this Consent Order, once approved, shall constitute a public record which may be disseminated as a disciplinary action of the Board. If this Consent Order is not approved, it shall not constitute an admission against interest in this proceeding, or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

This 29th day of March, 2019.

THE GEORGIA STATE BOARD OF PHARMACY ACT 1881 AMENDED 1889

(BOARD SEAL)

GEORGIA STATE BOARD OF PHARMACY

BY: William Prather
WILLIAM PRATHER, Pharm.D.
President with express permission by
Tanja Battle, Executive Director

ATTEST: Tanja D. Battle
TANJA D. BATTLE
Executive Director

(signatures continue on next page)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	**File No.:** **18-54-012130**
vs.	
Marley Drug Inc. **Respondent**	

CONSENT AGREEMENT AND ORDER

PARTIES

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **Marley Drug Inc.** ("Respondent") stipulate as follows in settlement of the above-captioned case.

APPLICABLE LAW

1. This matter is before the State Board of Pharmacy ("Board") pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and/or the Act of July 2, 1993, P.L. 345, No. 48 ("ACT 48"), *as amended*, 63 P.S. §§ 2201-2207.

LICENSURE STATUS

2. At all relevant and material times, Respondent held the following registration to practice as a non-resident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000542, which was originally issued on July 27, 2016, and which is currently set to expire on August 31, 2019.

STIPULATED FACTS

3. The Respondent admits that the following allegations are true:

a. Absent additional Board action, Respondent's registration may be continually reactivated, renewed, or reinstated upon the filing of the appropriate documentation and payment of the necessary fees.

b. Respondent's last known office address, as on file with the Board is: 5008 Peters Creek Parkway, Winston Salem, NC 27127.

c. At all relevant and material times, Respondent was authorized to practice as a non-resident pharmacy in the State of Alabama, permit number 114311.

d. On or about November 30, 2017, the Alabama State Board of Pharmacy ("Alabama Board"), by way of Consent Order at Alabama Board Case No. 17-L-0073, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Alabama because Respondent dispensed medications into the State of Alabama without a current or valid permit to do so during 2015, 2016 and/or up to and including July, 2017.

e. Pursuant to the November 30, 2017 Consent Order, Respondent was ordered to pay an administrative fine in the amount of $30,000.00.

ALLEGED VIOLATIONS

4. The Commonwealth alleges that the Board is authorized to suspend or revoke, or otherwise restrict Respondent's license under Sections 5(a) & (8) of the Act, 63 P.S. §§ 390-5(a) & 390-8; or impose a civil penalty under Sections 5(a) & (8) of the Act, 63 P.S. §§ 390-5(a) & 390-8, and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4); and/or impose the costs of investigation under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), because Respondent violated the Act at Section 5(b)(7), 63 P.S. § 390-5(b)(7), in that Respondent had a license to practice

pharmacy suspended, revoked or refused, or received other disciplinary action by the proper pharmacist licensing authority of another state, territory or country.

PROPOSED ORDER

5. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:

a. The Board finds that it is authorized to suspend or revoke, or otherwise restrict Respondent's license under Sections 5(a) & (8) of the Act, 63 P.S. §§ 390-5(a) & 390-8; or impose a civil penalty under Sections 5(a) & (8) of the Act, 63 P.S. §§ 390-5(a) & 390-8, and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4); and/or impose the costs of investigation under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), because Respondent violated the Act at Section 5(b)(7), 63 P.S. § 390-5(b)(7), in that Respondent had a license to practice pharmacy suspended, revoked or refused, or received other disciplinary action by the proper pharmacist licensing authority of another state, territory or country.

PUBLIC REPRIMAND

b. A **PUBLIC REPRIMAND** shall be placed on Respondent's permanent disciplinary record with the Board.

CIVIL PENALTY

c. A **CIVIL PENALTY** of three thousand dollars ($3,000.00) is levied upon Respondent. Respondent shall tender the full sum of three thousand dollars ($3,000.00) with this executed Consent Agreement and shall be paid by certified check, cashier's check, attorney's check, or money order issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc.). Payment shall be made payable to the "Commonwealth of

Pennsylvania," and shall be valid for a period of at least one hundred eighty (180) days. Respondent agrees that payment shall only be made by one of the methods indicated above and shall not be made by uncertified personal or corporate check.

d. This Order constitutes disciplinary action by the Board and shall be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action by the Board.

e. This case shall be deemed settled and discontinued upon the Board issuing an Order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

6. Respondent agrees that if Respondent is charged with a violation of an Act enforced by this Board in the future, this Consent Agreement and Order shall be admitted into evidence without objection in that proceeding.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

7. Respondent acknowledges the filing of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter, and knowingly and voluntarily waives the following rights related to that hearing: to be represented by counsel at the hearing; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any final adverse decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

8. Respondent acknowledges that she is aware that she has the right to consult with, and/or be represented by, private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering and accepting the terms of this Consent Agreement. To the extent

that Respondent is not represented by legal counsel, Respondent has knowingly elected to proceed without the assistance of legal counsel.

WAIVER OF CLAIM OF COMMINGLING AND OTHER CONSTITUTIONAL CLAIMS

9. Respondent expressly waives any constitutional rights and issues, such as commingling of prosecutorial and adjudicative functions by the Board or its counsel, which may arise or have arisen during the negotiation, preparation and/or presentation of this Consent Agreement. Respondent specifically agrees that if the Board rejects this agreement, it may assume that the facts and averments as alleged in this Consent Agreement are true and correct for the limited purpose of recommending a sanction, based on those assumed facts, that would be acceptable to the Board before hearing the case. In the event that the Board does assume the facts and averments as alleged in this Consent Agreement are true for purposes of making a recommendation as to an acceptable sanction, such action shall not constitute commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Respondent expressly waives any constitutional rights and issues related to alleged commingling, bias, or violation of due process rights to have an unbiased and impartial adjudicator in any subsequent hearing. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at hearing unless otherwise separately stipulated. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

NO MODIFICATION OF ORDER

10. Respondent agrees, as a condition of entering into this Consent Agreement, not to seek modification at a later date of the Stipulated Order adopting and implementing this Consent Agreement without first obtaining the express written concurrence of the Prosecution Division.

AGREEMENT NOT BINDING ON OTHER PARTIES

11. The Office of General Counsel has approved this Consent Agreement as to form and legality; however, this Consent Agreement shall have no legal effect unless and until the Board issues an Order approving and adopting this Consent Agreement.

EFFECT OF BOARD'S REJECTION OF CONSENT AGREEMENT

12. Should the Board not approve this Consent Agreement, presentation to and consideration of this Consent Agreement and other documents and matters by the Board shall not prejudice the Board or any of its members from further participation in the adjudication of this matter. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

AGREEMENT DOES NOT PREVENT ADDITIONAL DISCIPLINE BASED ON OTHER COMPLAINTS

13. Nothing in this Order shall preclude the Prosecution Division for the Commonwealth from filing charges or the Board from imposing disciplinary or corrective measures for violations or facts not contained in this Consent Agreement;

ENTIRE AGREEMENT

14. This agreement contains the whole agreement between the participants; provided however, that the captions printed in the various provisions of this agreement are for ease of reading only and are not to be interpreted as forming any part of this agreement. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.

VERIFICATION OF FACTS AND STATEMENTS

15. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information and belief. Respondent

understands that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. § 4904 relating to unsworn falsification to authorities.

Alissa C. C. Harrison
Prosecuting Attorney

DATED: 4/3/19

Marley Drug Inc.
Respondent

DATED: 3/29/19

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **MARLEY DRUG**
Registration Number: 0214-001534
Case Number: 194916

ORDER OF MANDATORY SUSPENSION

In accordance with Virginia Code § 54.1-3434.3, the Virginia Board of Pharmacy received and acted upon evidence that the North Carolina Board of Pharmacy suspended the permit of Marley Drug to conduct a pharmacy in the State of North Carolina, which is the jurisdiction in which Marley Drug is located. A certified copy of the Consent Order is attached hereto as Commonwealth's Exhibit 1.

WHEREUPON, pursuant to Virginia Code § 54.1-3434.3, it is hereby ORDERED that the registration of Marley Drug to conduct a non-resident pharmacy delivering in the Commonwealth of Virginia is hereby SUSPENDED.

Upon entry of this Order, the registration of Marley Drug will be recorded as suspended. Should Marley Drug seek reinstatement of its registration after it has been reinstated by and holds a current unrestricted permit as a pharmacy from the North Carolina Board of Pharmacy pursuant to Virginia Code § 54.1-3434.3, it shall be responsible for any fees that may be required for the reinstatement of the registration prior to issuance of the registration to resume practice.

Pursuant to Virginia Code § 2.2-4023 and § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection or copying on request.

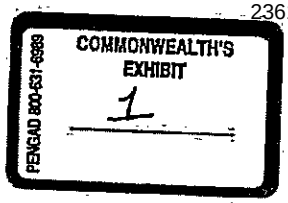
Caroline D. Juran, RPh, DPh, Executive Director
Virginia Board of Pharmacy

ENTERED:

4/10/19

CERTIFIED TRUE COPY
VIRGINIA BOARD OF PHARMACY

1300-1



BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: MARLEY DRUG, INC. (Permit No. 8320)	**CONSENT ORDER**

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for February 18, 2019 and, after appropriate notice, was heard on that day by Board Member Gene Minton at the office of the Board. Respondent Marley Drug, Inc. (hereinafter "Respondent" or the "Pharmacy") was present through its pharmacist-manager David Marley and represented by counsel Crystal Carlisle. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by its consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent Marley Drug, Inc., located at 5008 Peters Creek Parkway, Winston-Salem, North Carolina, is, and was at all relevant times referred to herein, the holder of Permit No. 8320. The Pharmacy is, and was at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. Between December 18, 2013 and April 3, 2018, the Pharmacy unlawfully dispensed and shipped prescriptions into Alabama, Arizona, Arkansas, California, Colorado, the District of Columbia, Georgia, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Utah, Vermont, West Virginia and Wyoming at times when the Pharmacy did not have a permit in those states.

4. Included among these prescriptions, between December 8, 2014 and March 8, 2017, were 33 controlled substance prescriptions that were unlawfully dispensed and shipped into Alabama (eleven schedule IV prescriptions), Arizona (five schedule III and IV prescriptions), California (ten schedule IV prescriptions), Georgia (one schedule IV prescription), Maryland (three schedule IV prescriptions), and Tennessee (two schedule III and IV prescriptions). These controlled substances were dispensed at times when the Pharmacy did not have a permit in those states and was not registered to dispense controlled substances into those states. The Pharmacy also did not report to those states' controlled substance prescription monitoring programs, as required by law.

5. The Pharmacy's pharmacist-manager testified that he had actual knowledge that the Pharmacy did not hold a permit in these states when the drugs were unlawfully dispensed and shipped, except for two states (Alabama and Maine) where he testified that, at least at certain times, he believed that the Pharmacy had a permit when its permit had actually lapsed.

However, the Board finds that it was unreasonable for the pharmacist-manager to believe that the Pharmacy had a permit in Alabama or Maine at any point when the Pharmacy did not have a permit, because the Pharmacy did not have a current permit for those states in its possession and publicly available information would have revealed that the Pharmacy did not have an active permit in those states at those times. Moreover, on January 9, 2018, the Pharmacy received notification from the Maine Board that (the Board finds) did or should have informed it that its Maine permit had not been renewed for 2018, but the Pharmacy nevertheless continued to ship into Maine until the permit was actually renewed on April 4, 2018.

6. As a mitigating factor as to shipments after December 14, 2016, on that date, the Pharmacy implemented remedial measures to attempt to ensure that prescriptions were not shipped into Arizona, Arkansas, California, the District of Columbia, Idaho, Louisiana, Maryland, Michigan, Montana, Nebraska, Oklahoma, Oregon and West Virginia until permits were secured. These measures did dramatically reduce the number of shipments over the prior time when the Pharmacy intended to ship without permits, but the Pharmacy still did make a relatively small number of unlawful shipments despite these efforts.

7. Between March 2016 and July 2017, the Pharmacy regularly and unlawfully held itself out in radio advertising as a permitted pharmacy in certain states at times when, in fact, it was not permitted to operate as a pharmacy. These violations are as follows:

a. In March 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the Commonwealth of Pennsylvania by advertising on 63 occasions on a radio station in Pittsburgh;

b. Between July and September 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Illinois by advertising on 53 occasions on radio stations in Chicago;

c. Between July and December 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of California by advertising on

707 occasions on radio stations in Los Angeles, Sacramento and San Francisco;

d. During November and December 2016, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Louisiana by advertising on 200 occasions on radio stations in New Orleans;

e. During December 2016 and January 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Oregon by advertising on 170 occasions on a radio station in Portland;

f. Between February and July 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Alabama by advertising on 79 occasions on radio stations in Gadsden and Mobile;

g. Between March and June 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Arkansas by advertising on 79 occasions on a radio station in Fort Smith; and

h. In June 2017, the Pharmacy unlawfully held itself out as permitted to dispense in the State of Michigan by advertising on 36 occasions on a radio station in Grand Rapids.

All advertisements run on and before December 14, 2016 were intentionally placed by the Pharmacy in states in which the Pharmacy was not permitted. However, as a mitigating factor, the Board finds that – after December 14, 2016 – the Pharmacy had instructed its advertising agency not to run advertising in certain states at the times of certain advertisements, but the advertising was run in violation of these instructions. This mitigating factor applies only to eighteen (18) of the advertisements in California and eighteen (18) of the advertisements in Louisiana on December 15 and 16, 2016; thirty-six (36) of the advertisements in Alabama from July 3 to 7, 2017; and all of the advertisements in Oregon, Arkansas and Michigan. However, the Pharmacy is still responsible for the actions undertaken on its behalf.

8. On October 5, 2017, the Maine Board of Pharmacy entered a Consent Order suspending the Pharmacy's permit in Maine for 90 days. The pharmacist-manager signed the Consent Order for the Pharmacy and testified he was aware that the Consent Order was entered.

Nevertheless, the Pharmacy violated this Consent Order by unlawfully shipping ten (10) prescriptions into the State of Maine during the period of the Pharmacy's suspension.

9. Between September 1, 2016 and October 27, 2017, the Pharmacy unlawfully operated in the State of Texas without a pharmacist-manager who was licensed as a pharmacist in Texas.

10. Between June 28, 2017 and November 21, 2017, the Pharmacy was disciplined by the States of Alabama, Idaho, Louisiana, Maryland, Oklahoma and Texas. In addition, on August 30, 2017, the Pharmacy's employee, R.Ph. Robert Brent Clevenger, was disciplined by the State of Oklahoma. The Pharmacy did not disclose that disciplinary action to other states in which it was permitted until its next renewal application in each of those states. The Pharmacy therefore violated the laws of the following states requiring that those states be notified of discipline within a certain number of days following the disciplinary action: Alaska (30 days after both Permit and Clevenger discipline), Colorado (30 days after Permit discipline), Connecticut (10 business days after Permit discipline), Georgia (five business days after Permit discipline), Illinois (60 days after both Permit and Clevenger discipline), Iowa (30 days after Permit discipline), Maine (10 days after Permit discipline), New Hampshire (30 days after Permit discipline), Oklahoma (10 days after Permit discipline), Pennsylvania (30 days after Permit discipline) and Tennessee (30 days after Permit and Clevenger discipline).

11. The Board incorporates by reference the following orders:

a. The Maryland Board of Pharmacy Pre-Charge Consent Order of June 28, 2017;

b. The Idaho Board of Pharmacy Stipulation and Consent Order of August 1, 2017;

c. The Oklahoma Board of Pharmacy Agreed Findings of Fact, Conclusions of Law and Final Order of August 30, 2017;

d. The Maine Board of Pharmacy Consent Agreement of October 5, 2017;

e. The Texas Board of Pharmacy Agreed Board Order of November 7, 2017;

f. The Louisiana Board of Pharmacy Consent Agreement of November 15, 2017;

g. The Alabama Board of Pharmacy Consent Order of November 30, 2017;

h. The California Board of Pharmacy Citation and Fine of January 18, 2018;

i. The Maine Board of Pharmacy Consent Agreement of March 28, 2018; and

j. The New Hampshire Board of Pharmacy Notice of Violation of January 7, 2019.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes. The statutes and rules that are at issue include, but are not limited to, N.C. Gen. Stat. §§ 90-85.38(a)(4), (6) and (7) and (b), 90-85.40(b) and (f) and 106-122(5); 21 NCAC 46 .1601(a) and (b), 46 .1804(a) and 46 .2501; Ala. Code §§ 20-2-51, 20-2-213, 34-23-30, 34-23-31 and 34-23-33; Ala. Admin. Code rr. 420-7-2-.12, 680-X-2-.07, 680-X-2-.12, 680-X-2-.22 and 680-X-3-.01; Alaska Stat. § 08.80.261; Alaska Admin. Code tit. 12, § 52.991;

Ariz. Rev. Stat. §§ 32-1901.01, 32-1927.02, 32-1927.03, 32-1929, 32-1961, 32-1965, 36-2522 and 36-2608; Ariz. Admin. Code §§ R4-23-502, R4-23-601 and R4-23-607; Ark. Code Ann. §§ 17-92-311, 17-92-401, 17-92-404 and 17-92-407; 070-00-002 Ark. Code R. § 02-04-0002; 070-00-004 Ark. Code R. §§ 04-00-0009, 04-00-0010, 04-00-0011 and 04-04-0001; Cal. Bus. & Prof. Code §§ 4051, 4110, 4112, 4113, 4120, 4156, 4301, 4302, 4303, 4340 and 17500; Cal. Health & Safety Code §§ 11165 and 11352.1; Cal. Code Regs. tit. 16, §§ 1709.1 and 1766; Colo. Rev. Stat. §§ 12-42.5-112, 12-42.5-116, 12-42.5-123, 12-42.5-126 and 12-42.5-130; Colo. Code Regs. §§ 719-1:1.00.00, 719-1:7.00.00 and 719-1:9.00.00; Conn. Gen. Stat. § 20-627(b)(8); D.C. Code §§ 47-2885.03 and 47-2885.10; D.C. Mun. Regs. tit. 22-B, § 1903; Ga. Code Ann. §§ 16-13-30, 16-13-35, 16-13-37, 16-13-59, 16-13-64, 26-4-40, 26-4-60, 24-4-80, 24-4-110, 26-4-112, 26-4-113 and 26-4-114.1; Ga. Comp. R. & Regs. 480-5-.03, 480-6-.02, 480-10-.02, 480-20-.01 and 480-48.02; Haw. Rev. Stat. §§ 461-11, 461-15 and 461-21; Haw. Code R. §§ 16-95-18 and 16-95-110; Idaho Code §§ 54-1721, 54-1726, 54-1729, 54-1732 and 54-1758; Idaho Admin. Code rr. 27.01.02.020, 27.01.02.030 and 27.01.02.050; 225 Ill. Comp. Stat. §§ 85/5, 85/15, 85/16a and 85/30; Ill. Admin. Code tit. 68, §§ 1330.30, 1330.40, 1330.550 and 1330.660; Iowa Code § 155A.13A; Iowa Admin. Code r. 657-19.10(155A); Ky. Rev. Stat. §§ 315.030, 315.035, 315.0351 and 315.121; 201 Ky. Admin. Regs. 2:205; La. Stat. Ann. §§ 37:1201, 37:1221, 37:1232 and 37:1241; La. Admin. Code tit. 46, part LIII, §§ 1101, 1105, 1115 and 2301-2309; Me. Rev. Stat. Ann. tit. 32, §§ 13731, 13742-a, 13751, 13752, 13753 and 13754; 02-392-8 Me. Code R. §§ 6 and 8; 02-392-11 Me. Code R. §§ 3 and 4; 02-392-13 Me. Code R. § 3; 02-392-30 Me. Code R. § 1; 02-392-31 Me. Code R. § 2; Md. Code Ann. Health-Gen. § 21-2A-03; Md. Code Ann. Health Occ. §§ 12-307, 12-313, 12-401, 12-403, 12-409, 12-703 and 12-704; Md. Code Ann. Crim. Law §§ 5-301, 5-307, 5-602 and 5-701; Md.

Code Regs. 10.19.03.03, 10.19.03.07, 10.34.10.01, 10.34.10.09, 10.34.37.04 and 10.47.07.03; Mich. Compl. Laws Ann. §§ 333.17711, 333.17741, 333.17748 and 333.1776; Mi. Admin. Code r. 338.477; Minn. Comp. Laws Ann. §§ 151.071, 151.18, 151.19 and 151.34; Minn. R. 6800.0110, 6800.0300, 6800.2250 and 6800.2400; Miss. Code Ann. §§ 73-21-97, 73-21-105 and 73-21-106; 30-20 Miss. Code R. §§ 3001:V, 3001:VI, 3001:VII and 3001:IX; Mont. Code Ann. §§ 37-7-321-to-323 and 37-7-703; Mont. Admin. R. 24.174.1001, 24.174.1003 and 24.174.2301; Neb. Rev. Stat. §§ 71-2407 and 71-2408; 172 Neb. Admin. Code §§ 128-007, 128-009 and 128-016; 175 Neb. Admin. Code §§ 8-003, 8-005 and 08-008; N.H. Rev. Stat. Ann. § 318:29; N.H. Code Admin R. Ph. 904.01; N.M. Stat. Ann. §§ 61-11-14, 61-11-15 and 61-11-20; N.M. Code R. §§ 16.19.6.24 and 16.19.27.7.B; Okla. Stat. tit. 59, §§ 353.17, 353.18, 353.24 and 353.26; Okla. Admin. Code §§ 535:10-3-1.1, 535:10-3-1.2, 535:15-3-2, 535:15-3-4.1, 535:15-3-4.2, 535:15-3-9, 535:25-7-3 and 535:25-9-3; Or. Rev. Stat. §§ 689.305, 689.335 and 689.405; Or. Admin. R. 855-006-0020; 855-019-0200, 855-019-0300, 855-019-0310, 855-041-1010, 855-041-1060 and 855-041-1095; 63 Pa. Cons. Stat. §§ 390-4.1, 390-5 and 390-8; 73 Pa. Cons. Stat. §§ 201-2 and 201-3; 49 Pa. Code §§ 27.18 and 27.71; Tenn. Code Ann. §§ 39-17-417, 53-10-304, 53-10-305, 53-11-302, 63-10-210 and 63-10-306; Tenn. Comp. R. & Regs. 1140-01-.02, 1140-01-.08, 1140-01-.11, 1140-02-.01, 1140-03-.02, 1140-03-.03 and 1140-11-.05; Utah Code Ann. §§ 58-17b-302, 58-17b-501, 58-17b-502 and 58-17b-618; Utah Admin. Code r. 156-17b-502 and 156-17b-603; Vt. Stat. Ann. tit. 26, §§ 2041, 2061 and 2064; 20 4 Vt. Code R. §§ 1400:1.11, 1400:6.1, 1400:6.2, 1400:7.5, 1400:16.8 and 1400:20.2; W. Va. Code §§ 30-5-2, 30-5-22, 30-5-23, 30-5-24 and 30-5-31; W. Va. Code R. §§ 15-1-14, 15-1-19, 15-1-20, 15-6-3 and 15-6-6 to -8; Wyo. Stat. Ann. § 33-24-152; 059.0001 4 Wyo. Code R. § 2; and 059.0001 19 Wyo. Code R. § 11.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The permit of Respondent Marley Drug, Inc. (Permit No. 8320) is hereby SUSPENDED for a period of ONE (1) MONTH, all of which is stayed for two (2) years from the date that the Board adopts this Order, upon the following conditions

a. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs (including, but not limited to, laws of the State of North Carolina and all other jurisdictions). Respondent specifically shall not dispense any drug, device or medical equipment that is shipped, mailed or delivered in any manner into any other jurisdiction without all required permits, registration and licenses;

b. Respondent shall violate no rules and regulations of the Board or any other Board of Pharmacy;

c. Respondent shall comply with all terms of this Order and any order of any other jurisdiction to which it is a party; and

d. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives as well as the board of any other jurisdiction (and its agents) in any investigation or inspection.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

This the 19th day of March, 2019.

NORTH CAROLINA BOARD OF PHARMACY

By: _____
Jack W. Campbell, IV
Executive Director

Marley Drug, Inc., the holder of permit number 27127, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Consent Order, and represents that it enters this Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel. The undersigned certifies that its agent executing this Consent Order is duly authorized to accept the Consent Order on behalf of Marley Drug, Inc., and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

MARLEY DRUG, INC.
(Permit No. ~~27127~~) 8320

By: _____ Date 3/7/19

Chris Holler
(Printed Name)

Its: Pharmacy Manager
(Position)

NORTH CAROLINA
Forsyth COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day, and acknowledged the due execution of the foregoing document: Chris Holler

Date: 3-7-2019

Rebecca S. Newman
Notary Public

Rebecca S. Newman
A Notary Public
Forsyth County, North Carolina
Exp: 4-17-2023

My commission expires: 4-17-2023

****

REJECTED BY:

_____ Date_____
MARLEY DRUG, INC.
(Permit No. 8320)

RECD WED APR 03 19

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 18-0393A

IN RE: Marley Drug Inc.
5008 Peters Creek Parkway
Winston-Salem, NC 27127
Permit NC2187

AGREED ORDER

The Kentucky Board of Pharmacy ("Board") and Marley Drug Inc. ("Respondent"), based upon the information presented and being sufficiently advised, hereby agree to the entry of this AGREED ORDER to obviate a formal hearing.

STIPULATIONS OF FACT

(1) Pursuant to KRS Chapter 315.0351, the Board is authorized to regulate and control matters related to out-of-state pharmacies located outside the Commonwealth of Kentucky that conduct business inside the Commonwealth.

(2) On or about November 14, 2018, Board staff was notified by the North Carolina Board of Pharmacy that Respondent shipped sildenafil, omeprazole, and pantoprazole into Kentucky without a Kentucky pharmacy permit, as required by KRS 315.0351(1).

(3) The Board's investigation revealed that Respondent shipped approximately 174 prescriptions into Kentucky from December 16, 2015 through December 1, 2016:

- The prescriptions included 27 prescriptions had a quantity dispensed of zero, leaving 148 prescriptions.
- Of the 148 prescriptions shipped, one hundred and forty five (145) were for Sildenafil 20mg tablets; one (1) Omeprazole 20mg capsules and two (2) Pantoprazole 40mg capsules.

(4) The above actions subject the Respondent to discipline pursuant to KRS 315.035(1).

(5) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent is fined $7,400.00, payable by April 27, 2019. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601.

(B) By entering into this AGREED ORDER, Respondent expressly acknowledges that it was fully and completely informed of its right to due process, that it fully understands those rights, and that it knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Craig Martin
President
Kentucky Board of Pharmacy

4/16/19
Date

Marley Drug, Inc.
Respondent

4/2/19
Date

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

April 26, 2019

Certified & Regular Mail
Elizabeth Marley, PharmD, Marley Drug Compliance Coordinator/Owner
Marley Drug, Inc,
5008 Peters Creek Parkway
Winston-Salem, NC 27127

RE: *Marley Drug, Inc, Permit #28RO00087000*

Dear Ms. Marley:

This letter is to advise you that the New Jersey State Board of Pharmacy (the "Board") has had an opportunity to review information concerning your practice of pharmacy following an investigation that uncovered the following infractions of the law and regulations:

At the April 24, 2019 meeting, the New Jersey Board of Pharmacy reviewed information supplied by Marley Drug, Inc (permit number 28RO00087000) regarding every prescription shipped into NJ prior to being licensed. The Board has determined to issue a fine of $15,000.00 ($1,000 x 15 for every prescription) to Marley Drug, Inc for every prescription shipped into NJ prior to being licensed.

The Board has determined that it will first offer you an opportunity to settle this matter and thereby avoid the initiation of formal disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the acknowledgment below and agree to the following:

Pay a penalty in the amount of ***$15,000.00 ($1,000 x 15 for every prescription shipped into NJ prior to being licensed),*** *(to be paid immediately upon your signing of the acknowledgment at the bottom of this letter.*

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. Any disposition by way a settlement will be a public record, and will have the same effect as an order of the Board. Any failure to comply with the terms to which you agree will be deemed a violation.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you either personally or with the assistance of an attorney will have an opportunity to respond to the charges and submit evidence and present testimony as may be necessary in order for the Board to make a final determination concerning the charges of unlawful activity.

You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order requiring you to pay costs incurred in the matter.

Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board of Pharmacy, at (973) 504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within fifteen (15) days, the Board's settlement offer will be withdrawn, and you will be deemed in default. The allegations against you will be deemed uncontested. The Board will then proceed to schedule the matter for final review and will enter an appropriate order. Once an order has been entered, your failure to pay any penalties may result in further action to suspend or revoke your license.

NEW JERSEY STATE
BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, R.Ph.
Executive Director

AR/sk

CERTIFICATION

I, Elizabeth Marley *, hereby acknowledge that I have read and reviewed the Board's letter dated* 4-26-2019 *regarding allegations of violations of the Board's enabling act and/or regulations.*

Please check one:

✓ *I acknowledge the conduct which has been charged and agree to: pay a penalty in the amount* ***$15,000.00*** *($1,000 x 15 for every prescription shipped into NJ prior to being licensed), (to be paid upon signing of this certification);*

I am also aware that the action taken against me by the Board here is a matter of public record, and that the Board's letter and this certification are public documents.

_____ *I hereby waive any rights I may have to a hearing in this matter in order to defend myself against any charges, but ask the Board to* ***consider my explanation*** *before rendering its final decision I understand that the Board may order any of the terms specified in its letter and that if does so I will be obligated to comply. I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents. Failure to comply may subject me to further disciplinary action and any failure to make a required payment will result in the filing of a certificate of debt.*

_____ ***I request a formal administrative hearing*** *to contest the charges specified in the UPL. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.*

Elizabeth Marley PharmD

Elizabeth Marley, PharmD/Owner

Dated:

Ref: *Elizabeth Marley, PharmD, Marley Drug Compliance Coordinator/Owner*
Marley Drug, Inc, Permit #28RO00087000
5008 Peters Creek Parkway
Winston-Salem, NC 27127

4/26/19 sk

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MARLEY DRUG, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2019-PHA-15281	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order pharmacy license of Marley Drug, Inc., in the State of Maine. The parties to this Consent Agreement are: Marley Drug, Inc. ("Marley Drug"), the Maine Board of Pharmacy ("the Board"), and the Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since March 24, 2016, Marley Drug has been licensed by the Board as a mail order pharmacy, license number MO40001812, located at 5008 Peters Creek Parkway in Winston Salem, North Carolina.

2. On October 5, 2017, Marley Drug entered into a consent agreement with the Board to resolve Case No. 2017-PHA-13348, pursuant to which consent agreement Marley Drug admitted to shipping 48 prescriptions to Maine patients prior to it becoming licensed by the Board as a mail order pharmacy in 2016 and agreed to pay a civil penalty of $24,000 and accept a 90-day license suspension, which would run from October 5, 2017, through January 4, 2018.

3. At midnight on December 31, 2017, Marley Drug's license expired because it failed to submit an application for renewal of its license.

4. On January 8, 2018, Marley Drug submitted an application for renewal, but because its license had already expired, its license would not renew until the application was approved by the Board.

5. In addition, Marley Drug disclosed for the first time in its renewal application disciplinary action taken against licenses it held in other jurisdictions. Marley Drug's failure to notify the Board of these disciplinary actions within 10 days as required by 10 M.R.S. § 8003-G(2)(C) was docketed by the Board as Complaint No. 2017-PHA-13930.

6. On March 28, 2018, Marley Drug entered into a consent agreement with the Board to resolve Complaint No. 2017-PHA-13930, pursuant to which consent agreement Marley Drug admitted to failing to report in a timely manner disciplinary action taken against licenses it held in other jurisdictions and agreed to pay a civil penalty of $9,000 with all but $3,000 suspended, a 540-day suspension, which was all suspended, and be placed on probation for one year, which period of probation commenced on March 28, 2018, and terminated on March 27, 2019.

7. Upon execution of the consent agreement in Complaint No. 2017-PHA-13930, the Board renewed Marley Drug's license effective April 4, 2018.

8. After the Board renewed Marley Drug's license, it received information from the North Carolina Board of Pharmacy that indicated Marley Drug had dispensed and shipped prescription drugs to Maine residents during periods when it did not hold an active license to do so in Maine.

9. During the period when its license was suspended from October 5, 2017, through December 31, 2017, Marley Drug dispensed and shipped 11 prescription drug orders to Maine residents.

10. During period when its license was expired from January 1, 2018, through April 3, 2018, Marley Drug dispensed and shipped 83 prescription drug orders to Maine residents.

11. On January 31, 2019, the Board filed a complaint against the license of Marley Drug alleging that it had dispensed and shipped 94 prescription drug orders to Maine residents when it did not hold an active license to so, which complaint was docketed as 2019-PHA-15281.

12. On April 4, 2019, the Board voted to offer Marley Drug this Consent Agreement in order to resolve Complaint No. 2019-PHA-15281.

13. Absent acceptance of this Consent Agreement by signing and dating it and returning it to William Akins, Complaint Office, Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333-0035 by May 17, 2019, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

14. Marley Drug admits to the facts as stated above and admits that such conduct constitutes grounds to impose discipline against its license pursuant to 10 M.R.S. § 8003(5-A)(A)(7) for continuing to act in a capacity requiring an active license under the Board after expiration or suspension of license.

15. As discipline for the conduct admitted to in paragraph 14 above, Marley Drug agrees to accept the following DISCIPLINARY ACTION:

a. A REPRIMAND;

b. A CIVIL PENALTY in the amount of ninety-four thousand dollars ($94,000.00), comprised of a $1,000.00 penalty for each prescription it dispensed and shipped to a Maine resident while its Maine license was either suspended or expired, which payment of the penalty shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Complaint Coordinator, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, at the time the signed Consent Agreement is submitted; and

c. LICENSE PROBATION for a period of two years, which period shall commence on the effective date of this consent agreement and during which period Marley Drug's license shall be subject to the following conditions:

   i. Marley Drug shall comply with all Maine pharmacy laws and Board rules; and

   ii. In the event of a failure to comply with the conditions of probation, and in addition to other sanctions permitted by law, Marley Drug shall be subject to the imposition of the $6,000 suspended civil penalty and/or the 540-day suspended license suspension imposed by the consent agreement that resolved Complaint No. 2018-PHA-13930.

16. Violation of any of the terms or conditions of this Consent Agreement by Marley Drug shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

18. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

19. Upon receipt of the signed Consent Agreement and the civil penalty payment, the Board will renew Marley Drug's license contingent upon it meeting all other eligibility criteria.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. The Board and Marley Drug agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Marley Drug fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Marley Drug and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving Marley Drug. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Marley Drug.

23. Marley Drug acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent

Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 4/25/19

MARLEY DRUG, INC.
d/b/a Marley Drug

By: _____

Title: CSO

DATED: 5/7/2019

JOSEPH BRUNO, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 5/10/2019

ANDREW L. BLACK
Assistant Attorney General

RECEIVED
JUL 17 2019
OREGON BOARD OF PHARMACY

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration of	)	Case No. 2019-0089
MARLEY DRUG INC	)	CONSENT ORDER
Registrant	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Disciplinary Action; Answer Required ("Notice"), hereby incorporated by reference, regarding the registrant in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the registrant as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the registrant is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the registrant admits that the facts alleged in the above-noted Notice are true, that legal cause exists pursuant to ORS 689.405 and ORS 689.445 for disciplinary action and imposition of a civil penalty by the Board; and

WHEREAS, the registrant consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The registrant shall pay the Board a civil penalty in the amount of $7,000 ($10,000 with $3,000 stayed pending no further violation of ORS 689.305 for three years). If respondent violates any term or condition of this Consent Order, within three years of the effective date of this Consent Order, the Board may take action to lift the stayed portion of the civil penalty. Payment of the $7,000 portion of the civil penalty not stayed to be made within ten days from the date this Consent Order becomes final.

2. Failure of the registrant to pay the civil penalty as required under this Consent Order may, after notice and hearing, result in further disciplinary action.

CONSENT

I hereby acknowledge that I am the authorized representative of registrant. On behalf of the registrant, I hereby acknowledge that I have read and understand the above-noted Notice and

the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

Authorized Representative
Marley Drug Inc
Registrant (Reg. No. RP-0003276)

7/15/19
Date

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Brianne Efremoff, Pharm.D, R.Ph.,
Compliance Director

7/18/19
Date

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of the Drug Outlet Registration	)	Case No. 2019-0089
MARLEY DRUG INC	)	NOTICE OF PROPOSED DISCIPLINARY ACTION; ANSWER REQUIRED
Registrant	)	

Under the authority granted pursuant to ORS 689.135, 689.145, 689.335, 689.405 and 689.445, the Oregon Board of Pharmacy proposes to take disciplinary action against your Certificate of Registration No. RP-0003276 because Marley Drug Inc violated the Oregon Pharmacy Act and the Board of Pharmacy rules as set forth below:

In or about March 2015 to April 20, 2017, Marley Drug Inc. provided drugs to residents in Oregon prior to receiving a drug outlet registration with the Board in violation of OAR 855-041-1060(2), ORS 689.305, and ORS 689.335 which is grounds for imposition of a civil penalty pursuant to ORS 689.832(1), 689.335(1), 689.405(1)(e)(B), and 689.445.

Based on these alleged violations, the Board proposes to impose a civil penalty in an amount of $10,000 per violation.

HEARING RIGHTS

The corporation is entitled to a hearing as provided by the Administrative Procedures Act (ORS chapter 183). An attorney must represent the corporation. If the corporation wishes to have a hearing, the corporation's attorney must file a written request for hearing with the Board within 21 days from the date this notice was mailed. The corporation's attorney may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax: (971) 673-0002

If a request for hearing is not received within this 21-day period, the corporation's right to a hearing shall be considered waived.

If the corporation requests a hearing, the corporation's attorney will be notified of the time and place of the hearing. Before the commencement of the hearing, the corporation will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing.

If the corporation does not request a hearing within 21 days, or if it withdraws a hearing request, notifies the Board or Administrative Law Judge that it will not appear, or fails to appear at a scheduled hearing, the Board may issue a final order by default imposing discipline. If the

Board issues a final order by default, it designates its file on this matter as the record.

ANSWER REQUIRED

Pursuant to OAR 855-001-0010 and OAR 855-001-0015, if you request a hearing you must also provide, within 21 days from the date this contested case notice was served, a written answer to the allegations set forth in this contested case notice. Your written answer must include an admission or denial of each factual matter alleged in the notice and a short and plain statement of each relevant affirmative defense you may have. Except for good cause, factual matters alleged in the notice and not denied in the answer shall be presumed admitted; failure to raise a particular defense in the answer will be considered a waiver of such defense; new matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and evidence shall not be taken on any issue not raised in the notice and the answer.

Hearing Request and Answers:
Consequences of Failure to Answer
855-001-0015

(1) A hearing request, and answer when required, shall be made in writing to the Board by the party or his attorney and an answer shall include the following:

- (a) An admission or denial of each factual matter alleged in the notice;
- (b) A short and plain statement of each relevant affirmative defense the party may have.

(2) Except for good cause;

- (a) Factual matters alleged in the notice and not denied in the answer shall be presumed admitted;
- (b) Failure to raise a particular defense in the answer will be considered a waiver of such defense;
- (c) New matters alleged in the answer (affirmative defenses) shall be presumed to be denied by the agency; and
- (d) Evidence shall not be taken on any issue not raised in the notice and the answer.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

Brianne Efremoff, Pharm.D, R.Ph., Compliance Director — Date 7/8/19

DATE OF MAILING 7-8-2019

AGREED BOARD ORDER #L-19-015

RE: IN THE MATTER OF
MARLEY DRUG, INC.
(PHARMACY LICENSE #28974)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28974 issued to Marley Drug, Inc. (Respondent), 5008 Peters Creek Parkway, Winston Salem, North Carolina, 27127.

By letter dated May 22, 2019, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Sections 565.002(a)(3) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2017), as alleged in the Counts below.

The conduct described in the disciplinary actions of the Maryland, Idaho, Oklahoma, Maine, Louisiana, Alabama, California, North Carolina and Georgia Boards of Pharmacy is substantially similar to conduct described in:

> Sections 560.001(b); 560.002(b); and 565.002(a)(3), (4) and (8) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2017);
>
> Sections 291.104(a)(1); and 315.6 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018); and
>
> Section 481.075(i) of the Texas Controlled Substances Act, TEX. HEALTH & SAFETY CODE ANN. (2017).

PREVIOUS HISTORY

On or about November 7, 2017, the Texas State Board of Pharmacy entered Agreed Board Order #K-17-034 in the matter of Marley Drug, Inc. The Order was based on allegations that the pharmacy operated as a non-resident pharmacy while not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas. The Order imposed a $1,000 penalty.

COUNTS

(1) On or about June 28, 2017, the Maryland Board of Pharmacy entered a Pre-Charge Consent Order against the Maryland non-resident pharmacy permit number P07484 held by Marley Drug, Inc. The Order was based on findings of fact that between November 2014, and December 2016, the pharmacy dispensed approximately 112 prescriptions to Maryland

patients when it did not possess a permit to operate as a pharmacy in Maryland. The Order imposed a $2,500 fine.

(2) On or about August 1, 2017, the Idaho Board of Pharmacy entered a Stipulation and Consent Order against the Idaho mail service pharmacy license number 44839MS held by Marley Drug, Inc. The Order was based on stipulations of fact that on 19 instances between May 2015, and December 2016, the pharmacy shipped prescription medications to Idaho patients when it did not possess a license to operate as a pharmacy in Idaho. The Order imposed a $7,600 fine.

(3) On or about August 30, 2017, the Oklahoma State Board of Pharmacy entered an Agreed Findings of Fact, Conclusions of Law and Final Order against the Oklahoma non-resident pharmacy license number 99-7152 held by Marley Drug, Inc. (licensed in Oklahoma as Marley Drug). The Order was based on findings of fact that from April 4, 2016, to December 12, 2016, the pharmacy shipped 76 prescriptions into Oklahoma when it did not possess a license to operate as a pharmacy in Oklahoma. The Order imposed a $7,600 fine.

(4) On or about October 5, 2017, the Maine Board of Pharmacy entered a Consent Agreement against the Maine mail order pharmacy license number MO40001812 held by Marley Drug, Inc. The Order was based on allegations that between November 24, 2014, and December 12, 2016, the pharmacy dispensed and shipped 48 prescriptions to patients in Maine when it did not possess a license to operate as a pharmacy in Maine. The Order imposed a reprimand, a 90-day suspension, and a $24,000 penalty.

(5) On or about November 15, 2017, the Louisiana Board of Pharmacy entered a Consent Order against the Louisiana non-resident pharmacy permit number 7512 held by Marley Drug, Inc. The Order was based on allegations that the pharmacy dispensed 344 prescriptions into Louisiana when it did not possess a license to operate as a pharmacy in Louisiana. The Order issued a letter of warning and imposed a $15,000 fine.

(6) On or about November 30, 2017, the Alabama State Board of Pharmacy entered a Consent Order against the Alabama non-resident pharmacy permit number 114311 held by Marley Drug, Inc. The Order was partially based on allegations set forth in a Statement of Charges and Notice of Hearing that during 2015, 2016, and 2017, the pharmacy dispensed medications into Alabama when it did not possess a permit to operate as a pharmacy in Alabama. The Order imposed a $30,000 fine.

(7) On or about January 16, 2018, the California State Board of Pharmacy issued a Citation and Fine against the California non-resident pharmacy license number 1940 held by Marley Drug, Inc. The Citation was based on allegations that between March 7, 2014, and March 7, 2017, the pharmacy shipped 1,443 prescriptions into California and advertised pharmacy services to California residents when it did not possess a license to operate as a pharmacy in California. The Citation imposed a $5,000 fine.

(8) On or about March 19, 2019, the North Carolina Board of Pharmacy entered a Consent Order against the North Carolina pharmacy permit number 8320 held by Marley Drug, Inc. The Order was partially based on findings of fact that between December 18, 2013, and April 3, 2018, the pharmacy dispensed and shipped prescriptions into 27 states and the District of Columbia when it did not possess a license to operate as a pharmacy in those states or in the District of Columbia, advertised pharmacy services in 8 states in which it was not licensed, and failed to report the dispensing of controlled substances to certain states' prescription monitoring programs. The Order imposed a one-month suspension stayed for two years contingent on the pharmacy complying with certain conditions.

(9) On or about March 29, 2019, the Georgia State Board of Pharmacy entered a Consent Order against the Georgia non-resident pharmacy license number PHNR000569 held by Marley Drug, Inc. The Order was based on findings of fact that from April 1, 2015, to June 8, 2015, the pharmacy shipped prescriptions into Georgia when it did not possess a license to operate as a pharmacy in Georgia. The Order imposed a $1,000 fine.

(10) On or about April 16, 2019, the Kentucky Board of Pharmacy entered an Agreed Order against the Kentucky non-resident pharmacy permit number NC2187 held by Marley Drug, Inc. The Order was based on stipulations that from December 16, 2015, through December 1, 2016, the pharmacy shipped approximately 14 prescriptions into Kentucky when it did not possess a permit to operate as a pharmacy in Kentucky. The Order imposed a $7,400 fine.

(11) On or about April 26, 2019, the New Jersey State Board of Pharmacy issued a Certification against the New Jersey non-resident pharmacy permit number 28R000087000 held by Marley Drug, Inc. The Certification was based on allegations that the pharmacy shipped 15 prescriptions into New Jersey when it did not possess a permit to operate as a pharmacy in New Jersey. The Certification imposed a $15,000 fine.

(12) On or about May 10, 2019, the Maine Board of Pharmacy entered a Consent Agreement against the Maine mail order pharmacy license number MO40001812 held by Marley Drug, Inc. The Agreement was partially based on allegations that from October 5, 2017, through April 3, 2018, the pharmacy dispensed and shipped 94 prescriptions into Maine when it did not hold an active license to operate as a pharmacy in Maine. The Agreement imposed a reprimand, a two-year probation, and a $94,000 penalty.

By letter dated May 22, 2019, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Dave Marley, Corporate President, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of August, 2019.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Dave Marley, Corporate President
On behalf of Marley Drug, Inc.

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: MARLEY DRUG
Registration Number: 0214-001534
Case Number: 195988

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Chris G. Holler, Pharmacist-in-Charge, as evidenced by their signatures hereto, in lieu of proceeding to informal conference, enter into the following Consent Order affecting Marley Drug's application for a registration to conduct a non-resident pharmacy dispensing in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On December 6, 2013, the Board issued Registration Number 0214-001534 to Marley Drug to conduct a non-resident pharmacy dispensing in the Commonwealth of Virginia. Said registration was suspended by Order of the Department of Health Professions pursuant to Virginia Code § 54.1-2409 on April 15, 2019. Marley Drug submitted an application for reinstatement of its registration to conduct a non-resident pharmacy dispensing in the Commonwealth of Virginia on May 13, 2019.

2. Marley Drug violated Virginia Code §§ 54.1-3434.3 and 54.1-3316(10) in that on March 19, 2019, Marley Drug entered into a Consent Order with the North Carolina Board of Pharmacy ("NC Board") in which the NC Board Ordered that Marley Drug's North Carolina permit be suspended for one month. The suspension was immediately stayed under terms and conditions ordered by the NC Board.

CONSENT

Marley Drug, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. Marley Drug has been advised to seek advice of counsel prior to signing this document;

2. Marley Drug is fully aware that without its consent, no legal action can be taken against it or its registration except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. Marley Drug acknowledges that it has the following rights, among others: the right to a formal administrative hearing before the Board; and the right to representation by counsel;

4. Marley Drug waives its right to a formal hearing;

5. Marley Drug admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. Marley Drug consents to the entry of the following Order affecting its right to conduct a non-resident pharmacy dispensing in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. The registration issued to Marley Drug to conduct a non-resident pharmacy dispensing in the Commonwealth of Virginia is REINSTATED contingent upon the following terms and conditions:

   a. Marley Drug shall comply with the terms and conditions of the Order of the North Carolina Board of Pharmacy dated March 19, 2019. Marley Drug shall advise this Board in writing of any change in that Order or in its status with the North Carolina Board of Pharmacy within ten calendar

days of such change. Marley Drug shall authorize free communication between this Board and the North Carolina Board.

b. Marley Drug shall provide a complete copy of this Order to the North Carolina Board of Pharmacy within 10 days of the entry of this Order and shall provide this Board with satisfactory evidence that it has done so within 10 days thereafter.

2. Marley Drug shall comply with all laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of pharmacy shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED: 8/22/19

SEEN AND AGREED TO:

Chris G. Holler, Pharmacist-in-Charge
Marley Drug

State of North Carolina
~~COMMONWEALTH OF VIRGINIA~~
COUNTY/CITY OF Forsyth Co., TO WIT:

Subscribed and sworn to before me, a notary public in and for ~~the Commonwealth of Virginia~~ State of North Carolina at large, on this 30 day of July, 2019.

CERTIFIED TRUE COPY
BY:
VIRGINIA BOARD OF PHARMACY

Tamara Lineberry
Notary Public

My commission expires: 3/25/23

Registration No:: _____

Tamara Lineberry
Notary Public
Davidson County, NC
My Commission Expires: 3/25/23

RECEIVED
AUG 23 2019
By

BEFORE THE BOARD OF PHARMACY
FOR THE STATE OF NEW MEXICO

IN THE MATTER OF:

Case No. 2018-086

MARLEY DRUG
5008 PETERS CEEK PKWY, WINSTON-SALEM, NC
License No. PH 3921

Respondent.

SETTLEMENT AGREEMENT

Whereas, MARLEY DRUG (hereafter, "Respondent") is licensed in New Mexico under the Pharmacy Act, NMSA 1978, Sections 61-11-1 through 61-11-29 ("the Act"), and is subject to the jurisdiction of the New Mexico Pharmacy Board ("Board"); and

Whereas, the Board received a formal complaint alleging that Respondent has violated the Act; and

Whereas, the Board found sufficient evidence to refer the matter to its administrative prosecutor and requested a Notice of Contemplated Action ("NCA") be issued against Respondent; and

Whereas, the parties have entered into a pre-NCA settlement agreement, but in the event the Board does not accept the agreement, an NCA will be issued pursuant to the Uniform Licensing Act, NMSA 1978, Sections 61-1-1 through -34 (1957, as amended through 2017) ("ULA"), which will state that the Board has sufficient evidence which, if not rebutted or satisfactorily explained, would justify the Board taking disciplinary action against Respondent up to and including license denial or revocation; and

Whereas, Respondent is willing to resolve this matter without the need for, and time and expense of, a formal hearing conducted; and

Whereas, the Board's administrative prosecutor believes that this proposed Settlement Agreement (the "Agreement") is appropriate and in the best interest of the Board:

THEREFORE, IT IS AGREED AS FOLLOWS:

1. Jurisdiction: Respondent is licensed by the Board or otherwise subject to the Act and jurisdiction of the Board.

2. Voluntary Agreement: Respondent enters into this Agreement knowingly and voluntarily, without duress or coercion, and after a full opportunity to consult an attorney. Respondent understands that if Respondent rejects this agreement the Board

will conduct a formal evidentiary hearing which could result in the Board imposing discipline that is more severe or less severe than the sanctions imposed herein.

3. Board Approval: This Agreement requires Board approval. If the Board rejects this Agreement, the Board may proceed with a full evidentiary hearing on a date scheduled by the Board in a subsequent notice. The approval shall be effective the date this Agreement is signed by the Board or its designee.

4. Waivers: If this Agreement is accepted by the Board, Respondent agrees to waive any and all rights under the Uniform Licensing Act, NMSA 1978, Sections 61-1-1 through -34 (1957, as amended through 2017), including but not limited to the right to an evidentiary hearing, the right to discovery, the right to present evidence, the right to call and cross examine witnesses, and the right to judicial review.

5. Violations: Respondent admits to the following violation(s) of the Act or Board's rules:

    i. Nineteen (19) violations of 16.19.6.24(B) NMAC, Non-Resident Pharmacies: Licensure requirement, no nonresident pharmacy shall ship, mail or deliver prescription drugs to a patient in this state unless licensed by the board. In addition, no nonresident pharmacy shall ship, mail or deliver controlled substances to a patient in this state unless registered by the drug enforcement administration and the board for controlled substances.
    ii. NMSA 61-11-20(A)(7): Procuring or attempting to procure registration as a pharmacist or pharmacist intern or licensure for a pharmacy or pharmaceutical business in this state for himself or another by knowingly making or causing to be made false representations to the board.

6. Sanctions and Conditions: Respondent agrees to the following disciplinary sanctions and conditions:

    a. Fine: Respondent shall pay to the Board a fine of two thousand three hundred and fifty dollars ($2,350.00) within ninety (90) days from the date this Agreement is accepted by the Board ($100 for each violation of non-resident pharmacy shipping medication into state without license, and $450 for the cost of the investigation).

7. Reportable Discipline: Respondent understands that this Agreement constitutes formal disciplinary action by the Board, and will be reported to the National Practitioner Data Bank.

8. Non-Compliance: Respondent understands and agrees that failure to comply with the terms of this Agreement will result in further Board action. Any violation of this Agreement will result in the immediate, automatic filing of an administrative Notice of

Non-Compliance by Board staff. Upon the filing of a Notice of Non-Compliance, the matter shall be scheduled for the next available public meeting of the Board, at which time the Board shall hear from Board staff regarding the alleged non-compliance. Respondent shall have the opportunity to address the allegations or offer any other relevant argument or evidence regarding the reasons for non-compliance. Such argument or evidence may be provided in writing prior to the meeting or in person at the Board meeting. Any presentation regarding the Notice of Non-Compliance shall be limited to evidence surrounding Respondent's alleged failure to comply with the Agreement. Upon finding such violation occurred, the Board may suspend Respondent's license(s), provided that this suspension may only remain in effect until such time as the Respondent has complied with the terms of this agreement, or take other enforcement action as permitted by law. If Respondent's non-compliance constitutes acts that are prohibited under the Board's statute or rules, the Board may also initiate a new disciplinary action and refer that matter for administrative prosecution.

9. Contact Information: Respondent shall notify the Board within ten (10) calendar days if there is a change in employment or home address during the term of discipline or prior to completion of any conditions stated herein.

10. Public Record: This Agreement and the original complaint are public records and may be provided for inspection if requested, pursuant to the New Mexico Inspection of Public Records Act ("IPRA"), NMSA 1978, Sections 14-2-1 to -12 (1947, as amended through 2018). The Board may also publish this Agreement or a summary of the Agreement to the public, which may include posting to the Board's website.

I understand and have read this document and hereby agree to the terms of this Agreement freely and voluntarily. I understand that by entering into this Agreement I am giving up my rights under the Uniform Licensing Act, including my right to an evidentiary hearing on the merits of the alleged violations.

I understand that if the Board accepts this Agreement, I am required to comply with the terms stated herein, and that failure to comply with the Agreement may subject me to further discipline, including temporary suspension of my license(s).

Respondent DAVID MARLEY, CEO

Date 7/24/19

Respondent's Attorney (if any)

Date

ORDER

This document is not valid unless it is accepted by vote of the Board. Having come before the Board during a properly scheduled public meeting, with a quorum present and majority voting in the affirmative, this Agreement is:

X ACCEPTED

IT IS SO ORDERED.

Richard Mazzoni, R.Ph., Chair
New Mexico Board of Pharmacy

8/23/19
Date

BEFORE THE WEST VIRGINIA BOARD OF PHARMACY

IN RE: **Complaint No. 2019-01-04**
Marley Drug, MO0561015

CONSENT AGREEMENT AND ORDER

Come now, Marley Drug, MO0561015 (hereinafter the "Respondent"), and the West Virginia Board of Pharmacy (hereinafter the "Board"), by its President, Dennis Lewis, and by counsel, Ryan Hatfield, for the purpose of agreeing to disciplinary action which shall be taken against Respondent by the Board, pursuant to West Virginia Code § 30-5-31. As reflected in this Consent Agreement and Order, the parties have reached an agreement concerning the proper disposition of this matter, and the Board, approving such agreement, does hereby **FIND** and **ORDER** as follows:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. The Board is a West Virginia State entity created by West Virginia Code § 30-5-1, *et seq.*, and is empowered to regulate the practice of pharmacy in order to protect the public interest, including its health, safety, and welfare.

2. Respondent, Marley Drug, holds license number MO0561015.

3. West Virginia Code § 30-5-31 states in relevant part that the Board has the power to revoke or suspend or otherwise discipline any license of any person who has, among other things, the following:

> (5) Having had a board authorization revoked or suspended, other disciplinary action taken, or an application for a board authorization revoked or suspended by the proper authorities of another jurisdiction;
>
> . . .
>
> (9) Violation of any laws, including rules pertaining thereto, of this or any other jurisdiction, relating to the practice of pharmacist care, drug samples, drug manufacturing, wholesale or retail drug or

device distribution, or controlled substances;

. . .

(11) Disciplinary action taken by another state or jurisdiction against a board authorization to practice pharmacist care based upon conduct by the licensee, registrant or permittee similar to conduct that would constitute grounds for actions as defined in this section[.]

4. Board Rule § 15-6 sets forth comprehensive licensure requirements for mail order and non-resident pharmacies.

5. In the instant case, the Board's investigation has determined that Respondent has been disciplined in other jurisdictions for violations that may warrant discipline in the State of West Virginia. Additionally, the Board's investigation has concluded that Respondent dispensed at least 296 prescription orders into West Virginia without first obtaining the appropriate licensure. Thus, discipline is warranted for violation of multiple Board laws and rules.

CONSENT

Marley Drug, Respondent, by freely and voluntarily affixing its representative's signature hereto, agrees, for the purposes of the entry of this Consent Agreement and Order, to the following:

1. Respondent acknowledges that it has the right to have counsel advise and/or represent it in this matter at his own expense; is aware of its option to pursue this matter through appropriate administrative and/or court channels, including, but not limited to, the right to have a formal hearing on the complaint against it; and to confront the witnesses and evidence against it; but intelligently and voluntarily waives its right to such a hearing in order to settle this matter as outlined herein.

2. Respondent understands that this will constitute formal discipline that will, as a matter of law, become a part of the public record and may, for the protection of the public, be reportable to others outside of the Board, including to any national database tracking discipline against those in the practice of pharmacy.

3. Having had an adequate opportunity to review this Consent Agreement and Order, and to receive such counsel and advice as it finds necessary and/or appropriate, including, but not limited to, access to legal counsel or the counsel of friends, relatives or other persons in the

Respondent's confidence, Respondent consents to the entry of this Consent Agreement and Order affecting its registration to operate a pharmacy licensed with the State of West Virginia.

ORDER

WHEREFORE, on the basis of the foregoing findings, conclusions, and Respondent's consent, the Board hereby **ORDERS** that:

1. This Consent Agreement shall constitute a formal **REPRIMAND** against Respondent's registration with the State of West Virginia.

2. Respondent shall be assessed a monetary fine of Thirty-Two Thousand and Five Hundred Dollars ($32,500.00). This amount represents a Three Thousand Dollar ($3,000.00) fine for the first violation, and One Hundred Dollars ($100.00) per violation thereafter. Such amount is to be made payable to the West Virginia Board of Pharmacy and is due and payable not later than ninety days from the date of entry of this Consent Agreement and Order.

4. Should proper cause arise or should law require, federal and state authorities shall be notified of this settlement via this Consent Agreement and Order.

ENTERED this 26 day of August, 2019

Marley Drug
By Authorized Representative
5008 Peters Creek Parkway
Winston-Salem, NC 27127

Dennis Lewis, President
West Virginia Board of Pharmacy
2310 Kanawha Blvd, East
Charleston, WV 25311

Ryan Hatfield (WV State Bar No. 12996)
General Counsel
West Virginia Board of Pharmacy
2310 Kanawha Blvd, East
Charleston, WV 25311
(304) 558-0558

STACIA M. SILVA 6760
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

DEPT OF COMMERCE
AND CONSUMER AFFAIRS
2020 JAN 23 P 2:33
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of	PHA 2019-94-L
MARLEY DRUG, INC.,	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1"-"13"
Respondent.	

241042211

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s) and Respondent MARLEY DRUG, INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy (hereinafter the "Board") under permit number PMP 1371. The permit was issued on or about January 17, 2017. The permit is set to expire or forfeit on or about December 31, 2019.

2. Respondent's mailing address for purposes of this action is 5008 Peters Creek Parkway, Winston-Salem, North Carolina 27127.

3. On or about November 13, 2017, Respondent reported it was disciplined in the States of Maryland, Idaho, Oklahoma, and Maine.

I HEREBY CERTIFY THAT THE ATTACHED
IS A TRUE AND CORRECT COPY OF THE
ORIGINAL ON FILE IN THE DEPARTMENT
OF COMMERCE & CONSUMER AFFAIRS.

4. A Pre-Charge Consent Order was filed on or about June 28, 2017 in Case No. PI-17-181 (hereinafter the "Maryland Order") (Exhibit "1"). The Maryland Order was based on the allegation that Respondent had dispensed prescription drugs to Maryland patients without a proper permit. Pursuant to the terms of the Maryland Order, Respondent was ordered to pay a fine of $2,500.00.

5. A Stipulation and Consent Order was filed on or about August 1, 2017 in Case No. BOP 17-061 (hereinafter the "Idaho Order") (Exhibit "2"). The Idaho Order was based on the allegation that Respondent had dispensed prescription drugs to Idaho patients without a proper license. Pursuant to the terms of the Idaho Order, Respondent was ordered to pay a fine of $7,600.00.

6. An Agreed Finding of Fact, Conclusions of Law and Final Order was filed on or about August 30, 2017 in Case No. 1466 (hereinafter the "Oklahoma Order") (Exhibit "3"). The Oklahoma Order was based on the allegation that Respondent had dispensed prescription drugs to Oklahoma patients without a proper license. Pursuant to the terms of the Oklahoma Order, Respondent was ordered to pay a fine of $7,600.00.

7. A Consent Agreement was filed on or about October 5, 2017 in Complaint No. 2017-PHA-13348 (hereinafter the "2017 Maine Order") (Exhibit "4"). The 2017 Maine Order was based on the allegation that Respondent had dispensed prescription drugs to Maine patients without a proper license. Pursuant to the terms of the 2017 Maine Order, Respondent's license was reprimanded, suspended for ninety (90) days, and they were ordered to pay a fine of $24,000.00.

8. On or about November 19, 2018, Respondent reported it was disciplined in the States of Louisiana, Alabama, and Maine.

9. A Consent Agreement was filed on or about November 15, 2017 in Case No. 17-0236 (hereinafter the "Louisiana Agreement") (Exhibit "5"). The Louisiana Agreement was based on the allegation that Respondent had dispensed prescription drugs to Louisiana patients without a proper permit. Pursuant to the terms of the Louisiana Agreement, Respondent was issued a Letter of Warning and ordered to pay a fine of $15,250.00.

10. A Consent Order was filed on or about November 30, 2017 in Case No. 17-L-0073 (hereinafter the "Alabama Order") (Exhibit "6"). The Alabama Order was based on the allegation that Respondent had dispensed prescription drugs to Alabama patients without a proper permit. Pursuant to the terms of the Alabama Order, Respondent was ordered to pay a fine of $30,000.00.

11. A Consent Agreement was filed on or about March 28, 2018 in Complaint No. 2018-PHA-13930 (hereinafter the "2018 Maine Order") (Exhibit "7"). The 2018 Maine Order was based on the allegation that Respondent had not timely reported disciplinary actions in six (6) states. Pursuant to the terms of the 2018 Maine Order Order, Respondent was reprimanded, placed on probation for one (1) year, and ordered to pay a fine of $9,000.00.

12. On or about February 4, 2019, Respondent reported it was disciplined in the State of New Hampshire.

13. A Notice of Violation was filed on or about January 28, 2019 (hereinafter the "New Hampshire Notice") (Exhibit "8"). The New Hampshire Notice was based on the allegation that Respondent had not timely reported disciplinary actions in five (5) states. Pursuant to the terms of the New Hampshire Notice, Respondent was ordered to pay a fine of $150.00.

14. On or about March 25, 2019, Respondent reported it was disciplined in the State of North Carolina.

15. A Consent Order was filed on or about March 19, 2019 (hereinafter the "North Carolina Order") (Exhibit "9"). The North Carolina Order was based on the allegation that Respondent had dispensed prescription drugs as well as advertised pharmacy services in several states without proper licensing and failed to report the dispensing of controlled substances to certain states' monitoring programs. Pursuant to the terms of the North Carolina Order, Respondent was suspended for one (1) month, which was stayed for two (2) years contingent on Respondent's compliance with the North Carolina Board of Pharmacy.

16. On or about April 8, 2019, Respondent reported it was disciplined in the State of Georgia.

17. A Consent Order was filed on or about March 29, 2019 in Docket No. 2019-0029 (hereinafter the "Georgia Order") (Exhibit "10"). The Georgia Order was based on the allegation that Respondent had dispensed prescription drugs to Georgia patients without a proper license. Pursuant to the terms of the Georgia Order, Respondent was ordered to pay a fine of $1,000.00.

18. An Agreed Order was filed on or about April 16, 2019 in Case No. 18-0393A (hereinafter the "Kentucky Order") (Exhibit "11"). The Kentucky Order was based on the allegation that Respondent had dispensed prescription drugs to Kentucky patients without a proper permit. Pursuant to the terms of the Kentucky Order, Respondent was ordered to pay a fine of $7, 400.00.

19. A Certification was filed on or about April 26, 2019 (hereinafter the "New Jersey Certification") (Exhibit "12"). The New Jersey Certification was based on the allegation that Respondent had dispensed prescription drugs to New Jersey patients without a proper license. Pursuant to the terms of the New Jersey Certification, Respondent was ordered to pay a fine of $15,000.00.

20. A Consent Agreement was filed on or about May 10, 2019 in Complaint No. 2019-PHA-15281 (hereinafter the "2019 Maine Order") (Exhibit "13"). The 2019 Maine Order was based on the allegation that Respondent had dispensed prescription drugs to Maine patients without a proper license. Pursuant to the terms of the 2019 Maine Order, Respondent was reprimanded, placed on probation for two (2) years, and ordered to pay a fine of $94,000.00.

21. RICO alleges Respondent was disciplined by the States of Maryland, Idaho, Oklahoma, Maine, Louisiana, Alabama, New Hampshire, North Carolina, Georgia, Kentucky, and New Jersey and that Respondent failed to timely report the actions from Maryland, Idaho, Oklahoma, Maine, Louisiana, and Alabama.

22. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency) and § 436B-19(15) (failure to timely report disciplinary action).

23. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent further understands that RICO enters into this Settlement Agreement, and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

6. Respondent represents Exhibit "1" is a true and correct copy of the Maryland Order.

7. Respondent represents Exhibit "2" is a true and correct copy of the Idaho Order.

8. Respondent represents Exhibit "3" is a true and correct copy of the Oklahoma Order.

9. Respondent represents Exhibit "4" is a true and correct copy of the 2017 Maine Order.

10. Respondent represents Exhibit "5" is a true and correct copy of the Louisiana Agreement.

11. Respondent represents Exhibit "6" is a true and correct copy of the Alabama Order.

12. Respondent represents Exhibit "7" is a true and correct copy of the 2018 Maine Order.

13. Respondent represents Exhibit "8" is a true and correct copy of the New Hampshire Notice.

14. Respondent represents Exhibit "9" is a true and correct copy of the North Carolina Order.

15. Respondent represents Exhibit "10" is a true and correct copy of the Georgia Order.

16. Respondent represents Exhibit "11" is a true and correct copy of the Kentucky Order.

17. Respondent represents Exhibit "12" is a true and correct copy of the New Jersey Certification.

18. Respondent represents Exhibit "13" is a true and correct copy of the 2019 Maine Order.

19. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

20. Respondent does not admit to violating any law or rule but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

21. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

22. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2019-94-L.

23. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes Chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Stacia M. Silva, Esq., 235 S. Beretania

Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraphs C.1. above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., and C.8. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Wailuku (City), HI (State), 11/18/19 (Date).

MARLEY DRUG, INC.
Respondent
By: _____ (Signature)
DAVID MARLEY (Print Name)
Its President / CEO

DATED: Honolulu, Hawaii, NOV 21 2019

STACIA M. SILVA
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF MARLEY DRUG, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1"-"13"; RICO CASE NO. PHA 2019-88-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

~~KERRI OKAMURA~~ ALANNA ISOBE
Chairperson

January 23, 2020
DATE

JULIE YURIE TAKISHIMA-LACASA
Vice Chair

MARY JO KEEFE

~~CAROLYN S. J. MA~~ SHERI TOKUMARU

~~ALANNA ISOBE~~

~~RONALD WEINBERG~~ CATALINA CROSS

KENNETH VANDENBUSSCHE

PVL 08/2018

STATE OF NC)
) SS.
COUNTY OF Davidson)

On this 18 day of November, 2019, before me personally appeared David Marley, to me known to be the person described, and who executed the foregoing instrument on behalf of MARLEY DRUG, INC. as its President / CEO, and acknowledged that he/she executed the same as his/her free act and deed.

This 6-page *Settlement Agreement Prior to Filing of Petition for Disciplinary Action and Board's Final Order* document dated November 18, 2019 (DATE DOCUMENT SIGNED BY RESPONDENT) was acknowledged before me by DAVID MARLEY (NAME OF PERSON SIGNING THIS DOCUMENT) this 18 day of November, 2019, in the City of Winston Salem, in the County of Davidson, in the _____ Circuit, in the State of NC.

Notary Signature: Kimberly E Grice
Print Notary Name: Kimberly E Grice
Notary Public, State of NC
My Commission expires: April 16, 2022

11C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy or* ☑ ***Ownership Change*** *(Provide current license number if making changes:* **PH** 04073

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: MedWiseRx

Physical Address: 1812 Centre Creek Drive Suite 115

Mailing Address: 228 Strawbridge Dr Suite 100 Moorestown, NJ 08057

City: Austin State: TX Zip Code: 78754

Telephone: 512-579-0026 Fax: 512-579-0008

Toll Free Number: 844-866-3730 (Required per NAC 639.708)

E-mail: mwr-aus@trhc.com Website: www.sinfoniarx.com

Managing Pharmacist: Chad Stonecipher License Number: 48046

OK VMS 6/30/21

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	Retail	☐	Off-site Cognitive Services
☐	Hospital (# beds_____)	☐	Parenteral **
☐	Internet	☐	Parenteral (outpatient)
☐	Nuclear	☐	Outpatient/Discharge
☐	Ambulatory Surgery Center	☐	Mail Service
☐	Community	☐	Long Term Care
☑	Other: Non-Dispensing	☐	Sterile Compounding **
		☐	Non Sterile Compounding
	All boxes must be checked	☐	Mail Service Sterile Compounding **
	For the application to be complete	☑	Other Services: Medication Therapy Management

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ■

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ■

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ■ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ■

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ■

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian W. Adams
Print Name of Authorized Person

8/18/20
Date

Board Use Only Date Processed:_____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware-Name of Pharmacy Owner: Tabula Rasa HealthCare Group, Inc.

Parent Company if any: Tabula Rasa HealthCare, Inc.

Mailing Address: 228 Strawbridge Drive Suite 100

City: Moorestown State: NJ Zip: 08057

Telephone: 866-648-2767 Fax: 856-235-0797

Contact Person: Richard Greene, VP Regulatory Affairs

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Tabula Rasa HealthCare Group, Inc. is owned 100% by Tabula Rasa HealthCare, Inc.
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? $0.0001 par value per share

4) What date did the corporation actually receive the cash assets? 6/30/2014

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 7 pm Saturday 8 am 4 pm

Sunday Closed am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

CareKinesis, Inc. changed its name to TRHC OpCo, Inc. on 1/1/2020. TRHC OpCo, Inc. changed its name to Tabula Rasa HealthCare Group, Inc. on 6/23/2020. Tabula Rasa HealthCare Group, Inc. owns the pharmacy MedWiseRx. See legal documents supporting this enclosed.

Posted April 1, 2020

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Brian W. Adams

Responsible Person of Tabula Rasa HealthCare Group, Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Brian W. Adams
Print Name of Authorized Person

8/18/20
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Jersey)
) ss.
Burlington COUNTY)

I, Brian W. Adams, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Secretary for Tabula Rasa HealthCare Group, Inc. (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Brian W. Adams, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
18th day of August, 2020.

NOTARY PUBLIC

COURTENAY L. SELLERS ★ NOTARY PUBLIC ★ NEW JERSEY

Courtenay L. Sellers
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50092284
MY COMMISSION EXPIRES October 16, 2023

Posted April 1, 2020

2420

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacist License # 48046

License Information

STONECIPHER, CHAD EDWIN

License Status Active
License # 48046
Expiration Date 11/30/2021
Date License Issued 09/29/2009

Pharmacist Details

School Graduated UNIVERSITY OF OKLAHOMA
Graduation Year 2000
Degree at time of licensure Pharm D
License Method Reciprocity
Preceptor Yes
Prior Disciplinary Order(s)* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Names

Last Name STONECIPHER
First Name CHAD
Middle Name EDWIN
Other Name
Certificate Name STONECIPHER, CHAD EDWIN

More Pharmacist Details

Specialty Board Certification ¥ Unknown

¥ Data regarding Specialty Board Certification is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder for clarification.

Remedial Plans and Drug Therapy Management

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Texas Pharmacist Employment information

Pharmacy Name	Pharmacy License #	Employment Status
MEDWISERX	33191	PIC

Page 1 of 0 | 20 | View 1 - 1 of 1

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

TEXAS STATE BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **33191** Expiration Date: **3/31/2022**

Balances: **0**

MEDWISERX
1812 CENTER CREEK DR STE 115
AUSTIN TX 78754

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TabulaRasa
HealthCare Group, Inc.

Officers – Directors

President - Director
Orsula V. Knowlton
[redacted] Spyglass Circle
Fernandina Beach, FL 32034-6579

Chief Executive Officer – Chairperson, Director
Calvin H. Knowlton
[redacted] Spyglass Circle
Fernandina Beach, FL 32034-6579

Secretary
Brian W. Adams
[redacted] Station Avenue
Haddonfield, NJ 08033

Work Address for all three:

228 Strawbridge Drive, Suite 100
Moorestown, NJ 08057-4600

TabulaRasa
HealthCare Group, Inc.

MedWiseRx
Description of Services

Patients with chronic illness face a number of challenges managing their day-to-day and long-term health, in part because medications are complex, confusing, costly and potentially dangerous. MedWiseRx was founded to optimize medication use and improve the health of patients with chronic illness by providing through Medication Therapy Management (MTM).

We offer a comprehensive approach to patient care and population health, with our team of dedicated pharmacists solely focused on providing medication reviews and clinical interventions to improve health, wellness and the management of chronic health conditions

MedWiseRx operates a pharmacist-run call center that provides phone-based medication therapy management (MTM) services. This is not retail or mail order pharmacy. It does not purchase, stock, compound, or dispense medications of any kind. Thus, it is not required to have either a state or federal controlled substance license.

The pharmacists make and receive calls to and from patients and physicians Monday through Friday from 8:00 am to 5:30 pm and Saturday from 9:00 am to 12:00 pm EST. However, pharmacist and healthcare providers have access to a pharmacist 24 hours per day, 7 days a week, toll-free at 844-866-3735.

The pharmacy complies with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. All patient records are only available to personnel as needed to provide service to patients. Paper records are kept in a secure storage system within the pharmacy.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TABULA RASA HEALTHCARE GROUP, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF JANUARY, A.D. 2021.

Jeffrey W. Bullock, Secretary of State

4674249 8300

SR# 20210185403

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202342392

Date: 01-21-21

TabulaRasa
HealthCare Group, Inc.

Change of Ownership to Tabula Rasa HealthCare Group, Inc. (formerly) TRHC OpCo, Inc. dba MedWiseRx

RE: Explanation of Change of Ownership for Applicant

SinfoniaRx, Inc. was merged into TRHC OpCo, Inc. resulting from a company-wide reorganization on 1/1/2020. This reorganization resulted in a change in ownership changing the EIN from: 90-1014939 to 26-4642609. At the same time, the name of the pharmacy changed from SinfoniaRx to MedWiseRx. Therefore, the enclosed Change in Ownership/Change in Name application is attached.

On June 23, 2020 TRHC OpCo, Inc. legally changed its name to Tabula Rasa HealthCare Group, Inc. Neither the parent company (Tabula Rasa Health Care, Inc.) nor the officers have changed. This was a name change of the owner of the pharmacy and not a change in ownership.

The new name of the pharmacy is MedWiseRx. The physical location of the pharmacy is 1812 Center Creek Drive, Suite 115, Austin Texas 78754.

The enclosed application and attachments provide a full documentation of the above events.

MedWiseRx is a non-dispensing pharmacy that provides medication therapy management services.

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:56 PM 12/20/2019
FILED 04:56 PM 12/20/2019
SR 20198800595 - File Number 4674249

CERTIFICATE OF AMENDMENT

TO THE FOURTH AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

CAREKINESIS, INC.

CareKinesis, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Corporation**"), hereby certifies as follows:

1. Article First of the Fourth Amended and Restated Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as follows:

"The name of the Corporation is TRHC OpCo, Inc. (the "Corporation")."

2. The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed this 20th day of December, 2019.

CAREKINESIS, INC.

By: _____
Name: Brian W. Adams
Title: Chief Financial Officer and Secretary

Certificate No. 1 For 100 Shares Issued to Tabula Rasa Healthcare Inc Transferred from / /20

Dated _____, 20____ Receipt acknowledged _____

No. Original Certificate	No Original Shares	No. Of Shares Transferred

NUMBER ** 1 **

INCORPORATED UNDER THE LAWS OF

SHARES ** 100 **

THE STATE
OF DELAWARE



CAREKINESIS, INC.

Authorized Common Stock 100 Shares, $0.0001 Par Value Per Share

This Certifies that **Tabula Rasa Healthcare, Inc.** is the owner of

One Hundred (100) fully paid

and non-assessable Shares of the Capital Stock of the above named Corporation transferable only on the books of the Corporation by the holder hereof in person or by duly authorized Attorney upon surrender of this Certificate properly endorsed.

In Witness Whereof, the said Corporation has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed this 20th day of June 20 14

TREASURER/SECRETARY

PRESIDENT

© 2011 ALLSTATE LEGAL® A DIVISION OF ALLSTATE INTERNATIONAL, INC. www.aslegal.com 800.222.0510 99C13

EXPLANATION OF ABBREVIATIONS

The following abbreviations, when used in the inscription of ownership on the face of this certificate, shall be construed as if they were written out in full according to applicable laws or regulations. Abbreviations, in addition to those appearing below, may be used

JT TEN	As joint tenants with right of survivorship and not as tenants in common	TEN ENT	As tenants by the entireties
TEN COM	As tenants in common	UNIF GIFT MIN ACT	Uniform Gifts to Minors Act
		CUST	Custodian for
		UNIF TRANS MIN ACT	Uniform Transfers to Minors Act

For Value Received, _____ *hereby sell, assign and transfer unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

_____ *Shares represented by the within Certificate, and do hereby irrevocably constitute and appoint*

_____ *Attorney to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.*

Dated _____ 20___

In presence of

_____ _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.



THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE TRANSFERRED EXCEPT (A) PURSUANT TO AN EFFECTIVE REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS, OR (B) IN A TRANSACTION WHICH IS EXEMPT FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:11 PM 12/23/2019
FILED 04:11 PM 12/23/2019
SR 20198827796 - File Number 4674249

CERTIFICATE OF MERGER

MERGING

SINFONÍARX, INC.
(an Arizona corporation)

WITH AND INTO

TRHC OPCO, INC.
(a Delaware corporation)

(Pursuant to Section 252 of the
Delaware General Corporation Law)

TRHC OpCo, Inc., a Delaware corporation, hereby executes this Certificate of Merger for the purpose of merging SinfoníaRX, Inc., an Arizona corporation ("SinfoníaRX"), with and into TRHC OpCo, Inc. (the "Merger") pursuant to the provisions of Section 252 of the Delaware General Corporation Law (the "DGCL"):

1. The names and states of incorporation of the constituent corporations in the merger (the "Constituent Corporations") are as follows:

Name	State of Incorporation
SinfoníaRX, Inc.	Arizona
TRHC OpCo, Inc.	Delaware

2. An Agreement and Plan of Merger, dated as of the date hereof, has been approved, adopted, certified, executed and acknowledged by each of the Constituent Corporations in accordance with Section 252 of the DGCL.

3. The name of the surviving corporation is TRHC OpCo, Inc. (the "Surviving Corporation").

4. The Certificate of Incorporation of the Surviving Corporation shall be the Certificate of Incorporation of TRHC OpCo, Inc. as in effect on the date hereof.

5. This Certificate of Merger, and the merger provided for herein, shall become effective on January 1, 2020 at 12:00 a.m.

6. The Agreement and Plan of Merger is on file at 228 Strawbridge Drive, Suite 100, Moorestown, NJ 08057, the place of business of the Surviving Corporation.

7. A copy of the Agreement and Plan of Merger will be furnished by the Surviving Corporation on request, without cost, to any stockholder of either of the Constituent Corporations.

8. The authorized capital stock of SinfoníaRX is: 100,000 shares of common stock, no par value per share.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Surviving Corporation has caused this Certificate of Merger to be signed by its duly authorized officer this 23rd day of December, 2019.

TRHC OPCO, INC.

By: _____
Name: Brian W. Adams
Title: Chief Financial Officer and Secretary

[Signature Page to Certificate of Merger]

CERTIFICATE OF AMENDMENT

TO THE FOURTH AMENDED AND RESTATED

CERTIFICATE OF INCORPORATION

OF

TRHC OPCO, INC.

TRHC OpCo, Inc., a corporation organized and existing under the laws of the State of Delaware (the "**Corporation**"), hereby certifies as follows:

1. Article First of the Fourth Amended and Restated Certificate of Incorporation of the Corporation is hereby amended and restated in its entirety to read as follows:

> "The name of the Corporation is Tabula Rasa HealthCare Group, Inc. (the "Corporation")."

2. The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

[SIGNATURE PAGE FOLLOWS]

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:33 AM 06/23/2020
FILED 10:33 AM 06/23/2020
SR 20205843172 - File Number 4674249

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed this 23rd day of June, 2020.

TRHC OPCO, INC.

By: _____
Name: Brian W. Adams
Title: Chief Financial Officer and Secretary

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

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

January 23, 2020

Corporation Service Company
211 E. 7th Street, Suite 620
Austin, TX 78701 USA

RE: TRHC OpCo, Inc.
File Number: 803507469

Assumed Name:
MedWiseRx

File Date: 01/22/2020

It has been our pleasure to file the assumed name certificate for the above referenced entity. Enclosed is the certificate evidencing filing. Payment of the filing fee is acknowledged by this letter.

If we can be of further service at any time, please let us know.

Sincerely,

Corporations Section
Business & Public Filings Division
(512) 463-5555

Enclosure

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

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

CERTIFICATE OF FILING
OF

TRHC OpCo, Inc.
File Number: 803507469
Assumed Name:
MedWiseRx

The undersigned, as Secretary of State of Texas, hereby certifies that the assumed name certificate for the above named entity has been received in this office and filed as provided by law on the date shown below.

ACCORDINGLY the undersigned, as Secretary of State, and by virtue of the authority vested in the secretary by law hereby issues this Certificate of Filing.

Dated: 01/22/2020

Effective: 01/22/2020

Ruth R. Hughs
Secretary of State

Form 503
(Revised 08/19)

Return in duplicate to:
Secretary of State
P.O. Box 13697
Austin, TX 78711-3697
512 463-5555
FAX: 512 463-5709
Filing Fee: $25

Assumed Name Certificate

This space reserved for office use.

FILED
In the Office of the
Secretary of State of Texas

JAN 22 2020

Corporations Section

Assumed Name

1. The assumed name under which the business or professional service is, or is to be, conducted or rendered is: MedWiseRx

Entity Information

2. The legal name of the entity filing the assumed name is:

TRHC OpCo, Inc.

State the name of the entity as currently shown in the records of the secretary of state or on its organizational documents, if not filed with the secretary of state.

3. The entity filing the assumed name is a: (Select the appropriate entity type below.)

- ☑ For-profit Corporation
- ☐ Nonprofit Corporation
- ☐ Professional Corporation
- ☐ Professional Association
- ☐ Limited Liability Company
- ☐ Limited Partnership
- ☐ Limited Liability Partnership
- ☐ Cooperative Association
- ☐ Other _____

Specify type of entity. For example, foreign real estate investment trust, state bank, insurance company, etc.

4. The file number, if any, issued to the entity by the secretary of state is: 803507469

5. The state, country, or other jurisdiction of formation of the entity is: Delaware

6. The entity's principal office address is:

228 Strawbridge Drive, Suite 100
Street or Mailing Address

Moorestown	NJ	USA	08057
City	*State*	*Country*	*Postal or Zip Code*

Period of Duration

☑ 7a. The period during which the assumed name will be used is 10 years from the date of filing with the secretary of state.

OR

☐ 7b. The period during which the assumed name will be used is _____ years from the date of filing with the secretary of state (not to exceed 10 years).

OR

☐ 7c. The assumed name will be used until _____ (not to exceed 10 years).
mm/dd/yyyy

County or Counties in which Assumed Name Used

8. The county or counties where business or professional services are being or are to be conducted or rendered under the assumed name are:

☑ All counties

☐ All counties with the exception of the following counties: _____

☐ Only the following counties: _____

Execution

The undersigned signs this document subject to the penalties imposed by law for the submission of a materially false or fraudulent instrument and also certifies that the person is authorized to sign on behalf of the identified entity. If the undersigned is acting in the capacity of an attorney in fact for the entity, the undersigned certifies that the entity has duly authorized the undersigned in writing to execute this document.

Date: 1/22/20

Brian W. Adams, Chief Financial Officer and Secretary

Signature of a person authorized by law to sign on behalf of the identified entity (see instructions)

Print Reset

SinfoníaRx

1812 Centre Creek Drive, Suite 115, Austin, TX 78754 | T: 512-579-0026 | F: 512-549-0008

On December 18, 2019, the Oklahoma Board of Pharmacy (OK BOP) notified SinfoniaRx, Austin, (OK BOP Lic: 99-8497, TX BOP Lic: 32025) concerning a discrepancy in the Pharmacist-In-Charge listed on the Oklahoma Pharmacy license application for SinfoniaRx, Austin, TX. Due to an oversight, the pharmacy did not notify the OK BOP of the newly designated OK PIC. An Oklahoma licensed pharmacy was always on site and overseeing services provided to Oklahoma patients. The Oklahoma BOP has since been properly notified of the change in Oklahoma licensed pharmacist PIC. The matter was fully resolved by agreement with the Oklahoma Board of Pharmacy, January 14, 2020.

Sincerely,
SinfoniaRx

Richard B. Greene

Richard B. Greene
VP Regulatory Affairs
856-840-4821
rgreene@trhc.com

SinfoníaRx

1812 Centre Creek Drive, Suite 115, Austin, TX 78754 | T: 512-579-0026 | F: 512-549-0008

By way of background, SinfoniaRx was founded to optimize medication use and improve the health of patients with chronic illness by providing through Medication Therapy Management (MTM). Patients with chronic illness face a number of challenges managing their day-to-day and long-term health, in part because medications are complex, confusing, costly, and potentially dangerous.

SinfoniaRx operates a pharmacist-run call center that provides phone-based medication therapy management (MTM) services. This is not retail or mail order pharmacy. It does not purchase, stock, compound, or dispense medications of any kind. Thus, it is not required to have either a state of federal controlled substance license.

On December 18, 2019, the Oklahoma Board of Pharmacy (OK BOP) notified SinfoniaRx, Austin, (OK BOP Lic: 99-8497, TX BOP Lic: 32025) concerning a discrepancy in the Pharmacist-In-Charge listed on the Oklahoma Pharmacy license application for SinfoniaRx, Austin, TX. Various State Boards of Pharmacy require a non-resident pharmacy to have a state designated PIC pharmacist who is licensed in that state to oversee services provided to patients in that state. SinfoniaRx maintains a policy to always have a backup state licensed pharmacist on staff in case the designated pharmacist leaves the team.

The Oklahoma licensed pharmacist identified in the original Oklahoma non-resident pharmacy application resigned her position at SinfoniaRx after the application was completed and submitted to Oklahoma. Upon the pharmacy receiving the OK PIC resignation, the pharmacy immediately identified a new Oklahoma licensed pharmacist to become the OK PIC. Due to an oversight, the pharmacy did not notify the OK BOP of the newly designated OK PIC. It is important to note an Oklahoma licensed pharmacy was always on site and overseeing services provided to Oklahoma patients. The Oklahoma BOP has been properly notified of the change in Oklahoma licensed pharmacist PIC.

The matter was fully resolved by agreement with the Oklahoma Board of Pharmacy, January 14, 2020.

Please feel free to contact me if you desire any further information regarding this matter.

Sincerely,
SinfoniaRx

Richard B. Greene

Richard B. Greene
VP Regulatory Affairs
856-840-4821
rgreene@trhc.com

OKLAHOMA
State Board of Pharmacy
2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Marty Hendrick, Pharm. D., D.Ph., Executive Director
pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
Phone: 405.521.3815 • Fax: 405.521.3758

December 18, 2019

Sinfoniarx, Inc. #99-8494
Attn: Sylvia Guan
1812 Centre Creek Dr., Ste. 115
Austin, TX 78754

RE: OSBP vs. Sinfoniarx, Inc, #99-8494, Complaint & Case No. 1574

To Whom it May Concern:

A Complaint has been filed against you by the Oklahoma State Board of Pharmacy. The Complaint is enclosed with this letter. A hearing has been scheduled on the Complaint and your Notice of Hearing is also enclosed. At the hearing, the Board of Pharmacy members will be presented with the Complaint and the evidence for their consideration and then they will determine your innocence or guilt on the violations alleged in the Complaint. If guilt is established by clear and convincing evidence, the Board will then determine the penalty to be assessed under the penalties allowed in the Pharmacy Act. Please be advised that you have the right to have an attorney to represent you with regard to the allegations against you, you have the right to cross-examine witnesses, and you have the right to present witnesses and evidence in your own defense at the hearing.

Most times, a licensee will request a meeting with the Board of Pharmacy's Executive Director and a Compliance Officer at least á week prior to the hearing to give the licensee an opportunity to discuss the issues raised in the Complaint with the Director. Many times, the Director and licensee will attempt to reach an agreement as to how to resolve the issues raised in the Complaint without the necessity of a full hearing where all the evidence is presented in an open Board meeting. As a result of these discussions, often the licensee and Director will write an Agreed Order for the licensee's review and consideration. If the Agreed Order is accepted by the licensee and signed prior to the Board hearing, it will then be presented at the Board meeting for the Board members' consideration. This process does not require the evidence to be presented and the examination and cross-examination of witnesses to be done during the Board meeting, which is open to the public under the Open Meetings Act.

If you would like to schedule an informal meeting to review and discuss any of the issues raised in the Complaint with the Director of the Board and a Pharmacist Compliance Officer in an attempt to resolve the issues, please contact Senior Compliance Officer Gary LaRue, D.Ph., or myself before January 3, 2020 to schedule a meeting. Some licensees bring their attorney to this informal meeting, but it is certainly not a requirement. You always have the right to retain an attorney after the informal meeting. Please keep in mind that if you do bring your attorney to the informal meeting, the Board's Assistant Attorney General/prosecutor must also be present at the informal meeting. If an Agreed Order agreement is not reached during this informal meeting, your case will go to a full hearing at the Board meeting as now scheduled.

Again, please contact Gary LaRue, D.Ph., or myself by January 3, 2020 if you would like to schedule a meeting with the Board of Pharmacy Director and a Compliance Officer. Please feel

A Constitutional Board Established in 1907

President	Vice-President	Member	Member	Member	Member
Greg Adams, D.Ph.	Jim Spoon, D.Ph.	Mark St.Cyr, D.Ph.	Kyle Whitehead, D.Ph.	Jason Willeford	Justin Wilson, D.Ph.
Clinton	*Sand Springs*	*Jones*	*Enid*	*Norman*	*Norman*

OKLAHOMA
State Board of Pharmacy
2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Marty Hendrick, Pharm. D., D.Ph., Executive Director
pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
Phone: 405.521.3815 • Fax: 405.521.3758

free to call the Board office at 405-521-3815, if you have any questions or need clarification regarding any of the processes of the Board.

Sincerely,

Marty Hendrick

Marty Hendrick, PharmD, DPh
Executive Director

MH/rj

enclosures

A Constitutional Board Established in 1907

President	Vice-President	Member	Member	Member	Member
Greg Adams, D.Ph. *Clinton*	Jim Spoon, D.Ph. *Sand Springs*	Mark St.Cyr, D.Ph. *Jones*	Kyle Whitehead, D.Ph. *Enid*	Jason Willeford *Norman*	Justin Wilson, D.Ph. *Norman*

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
SinfoniaRx, Inc. **(License No. 99-8494)** **1812 Centre Creek Drive, Suite 115** **Austin, TX 78754**	)	**Case No.** 1574

COMPLAINT

COMES NOW, Gary LaRue, D.Ph., Deputy Director of the Oklahoma State Board of Pharmacy ("Board"), being first duly sworn upon oath, and alleges that Respondent, SinfoniaRx, Inc., (License No. 99-8494), has violated provisions of the Oklahoma Pharmacy Act, 59 O.S. §353.1 et seq., in the manner set forth below in Counts 1 through 3.

Pursuant to 59 O.S. §353.26(A), the violations described below authorize the Board to take disciplinary action against Respondent which may include revocation or suspension of Respondent's license. Pursuant to 59 O.S. §353.7(12), the Board has the power to levy fines not to exceed Three Thousand Dollars ($3000.00) for each count for which any holder of a certificate, license or permit has been found guilty in a Board hearing. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. Also pursuant to 59 O.S. §353.7(12), the Board is empowered to impose (singly or in combination) any of the following corrective disciplinary sanctions: extra continuing education ("CE"), attendance at live CE programs, participation in a rehabilitation program for the impaired.

FACTUAL ALLEGATIONS

1. On April 15, 2019, the Board received an application for a new pharmacy license from SinfoniaRx, Inc., (License No. 99-8494). The PIC listed on the application is Christa Tetuan, D.Ph., (Oklahoma License No. 18272). The license was not issued until June 28, 2019.

2. On October 21, 2019, the Board staff emailed Christa Tetuan with questions based on a phone call received from her. The Board staff asked if she was aware that the pharmacy listed her as the PIC on the application and informed her that it appeared she had signed the application as well. The Board staff also asked if she notified the Board within 10 days of leaving employment from the above named pharmacy.

3. The Board received an email from Saul Ortega, Pharmacy Director, for SinfoniaRx. The email stated that they were making a change in PIC and that Sylvia Guan, D.Ph., (Oklahoma License No. 18054), was replacing Christa Tetuan. Board staff requested that Mr. Ortega specify the date Christa Tetuan left her duties as PIC. On October 23, 2019, Mr. Ortega replied that Christa Tetuan left her duties as PIC on May 28, 2019, before the pharmacy license was issued and that Sylvia Guan immediately assumed the role of PIC. His reply went on to say that the pharmacy does not dispense or stock any medications and that they did not conduct an inventory to accompany this change in PIC. He also stated that they realized this oversight through an internal review.

4. On October 22, 2019, the Board received an email response from Christa Tetuan. The email stated that she was aware when signing the application that she would be designated as the PIC and that she never received any correspondence regarding submission of the application or processing.

5. Ms. Tetuan stated that she resigned from her position with SinfoniaRx on May 24, 2019, and was not aware that the pharmacy had been granted a license on June 28, 2019. She updated her address and employment online on June 6, 2019. When logging in online to update her home address with the Board on October 20, 2019, she learned that the pharmacy had received its license and that she was listed as the PIC. She was under the impression that SinfoniaRx had not yet submitted the application when she resigned and that they had designated another pharmacist for a new application.

6. On November 27, 2019, Deputy Director LaRue emailed Christa Tetuan and asked her if she notified Saul Ortega once she noticed that she was still listed as the PIC of SinfoniaRx. Tetuan's response was that she contacted Mr. Ortega by text and phone call on October 21, 2019 and informed him that he needed to change the PIC for the pharmacy.

7. Deputy Director LaRue does not believe that the pharmacy would have designated a new PIC until their license came up for renewal in June 2020 without the text and phone call from Christa Tetuan.

COUNT 1

Respondent is in violation of OAC 535:15-3-9. Non-resident pharmacies.

(b) Licensing requirements. A non-resident pharmacy shall:

(6) submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident's pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC.

Paragraphs 1 through 7 are incorporated by reference.

COUNT 2

Respondent is in violation of OAC 535:25-7-3. Registrant conduct.

(a) Registrants shall conduct business in conformity with all federal, state and municipal laws at all times.

Paragraphs 1 through 7 are incorporated by reference.

COUNT 3

Respondent is in violation of 535:25-9-3. Violating laws or rules.

A registrant shall not violate directly, (or indirectly, through actions of another), assist or abet in the violation of, or conspire to violate, any provision of the Oklahoma Pharmacy Act, 59, O.S. Section 353 et seq., the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Quality and Security

Act of 2013, the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules.

Paragraphs 1 through 7 are incorporated by reference.

Accordingly, the undersigned issues this Complaint on behalf of the Board on the 19th day of December, 2019.

Gary M. LaRue

Gary M. LaRue, D.Ph.
DEPUTY DIRECTOR
OKLAHOMA STATE BOARD OF PHARMACY

STATE OF OKLAHOMA)
) ss
COUNTY OF OKLAHOMA)

SUBSCRIBED AND SWORN to before me on this 19th day of December, 2019.

Rhonda Jenkins

NOTARY PUBLIC

My Commission Expires:

RHONDA JENKINS NOTARY # 00003203 EXP. 03/18/20 PUBLIC STATE OF OKLAHOMA

(Seal)

This copy is certified to be a "TRUE COPY" of the original document contained in the files of the Oklahoma State Board of Pharmacy.

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Sinfoniarx, Inc. #99-8494 **Attn: Sylvia Guan** **1812 Centre Creek Dr., Ste. 115** **Austin, TX 78754**	)	**Case No. 1574**
Respondent	)	

NOTICE OF COMPLAINT AND HEARING

1. This will advise you that a Complaint has been filed against you, Sinfoniarx, Inc. with the Executive Director of the Oklahoma State Board of Pharmacy (the "Board").

2. The Complaint, a copy of which is attached hereto and incorporated by reference, alleges facts, which if true, constitute violations of 59 O.S. § 353.1 et seq., the Oklahoma Pharmacy Act.

NOTICE OF HEARING

3. Pursuant to the power and jurisdiction of the Board granted by 59 O.S. §§ 353.7 and 353.26, a hearing before the Board has been set for the 15th day of January 2020, at 10:30 a.m.

4. The hearing will be held at the Board of Pharmacy offices located at 2920 Lincoln Boulevard, Suite A, Oklahoma City, Oklahoma 73105, on the allegations in the Complaint and the Board shall consider the evidence introduced by the State and by you, the Respondent. Applying the standard of clear and convincing evidence, the Board may suspend or revoke your license or permit, reprimand you, place you on probation, and or levy fines against you.

5. Any respondent who fails to appear as directed may be determined to have waived his right to present a defense to the charges alleged in the complaint. If the Board finds, after having reviewed the evidence, that the violation alleged did in fact occur, suspension, revocation or other disciplinary action may be ordered by the Board. OAC 535:1-7-4.

6. You have the right to legal counsel. You may appear with or without legal counsel.

7. Pursuant to 75 O.S. § 309, this hearing shall be your opportunity to respond and present evidence and argument on all issues involved.

8. Pursuant to the Oklahoma Administrative Procedures Act, these proceedings will be recorded. Said recording can be transcribed upon written request of the party. Cost of any such transcription shall be paid by the requesting party.

MARTY HENDRICK, PHARMD, DPh
EXECUTIVE DIRECTOR
OKLAHOMA STATE BOARD OF PHARMACY

STATE OF OKLAHOMA)
) ss
COUNTY OF OKLAHOMA)

SUBSCRIBED AND SWORN to before me on this 17th day of December, 2020.

NOTARY PUBLIC

My Commission Expires:

RHONDA JENKINS NOTARY # 00003283 EXP. 03/18/20 PUBLIC OF OKLAHOMA STATE

This copy is certified to be a "TRUE COPY" of the original document contained in the files of the Oklahoma State Board of Pharmacy.

RECEIVED
JAN 16 2020
OK STATE BOARD OF PHARMACY

COPY

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
SinfoniaRx, Inc.	)	
(License No. 99-8494)	)	**Case No. 1574**
1812 Centre Creek Drive, Suite 115	)	
Austin, TX 78754	)	

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on January 15, 2020, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Spoon, Wilson, Adams, Willeford and Whitehead were present. President Adams presided. John M. Settle, Chief Assistant Attorney General, served as prosecutor for the Board. Rose Martin, Pharm. D., Chief Operating Officer, appears on behalf of Respondent.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of the right to contest the allegations of the Complaint herein, to cross-examine witnesses, and to present witnesses and evidence in defense of the allegations of the Complaint. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. On April 15, 2019, the Board received an application for a new pharmacy license from SinfoniaRx, Inc., (License No. 99-8494). The PIC listed on the application is Christa Tetuan, D.Ph., (Oklahoma License No. 18272). The license was not issued until June 28, 2019.

2. On October 21, 2019, the Board staff emailed Christa Tetuan with questions based on a phone call received from her. The Board staff asked if she was aware that the pharmacy listed her as the PIC on the application and informed her that it appeared she had signed the application as well. The Board staff also asked if she notified the Board within 10 days of leaving employment from the above named pharmacy.

3. The Board received an email from Saul Ortega, Pharmacy Director, for SinfoniaRx. The email stated that they were making a change in PIC and that Sylvia Guan, D.Ph., (Oklahoma License No. 18054), was replacing Christa Tetuan. Board staff requested that Mr. Ortega specify the date Christa Tetuan left her duties as PIC. On October 23, 2019, Mr. Ortega

replied that Christa Tetuan left her duties as PIC on May 28, 2019, before the pharmacy license was issued and that Sylvia Guan immediately assumed the role of PIC. His reply went on to say that the pharmacy does not dispense or stock any medications and that they did not conduct an inventory to accompany this change in PIC. He also stated that they realized this oversight through an internal review.

4. On October 22, 2019, the Board received an email response from Christa Tetuan. The email stated that she was aware when signing the application that she would be designated as the PIC and that she never received any correspondence regarding submission of the application or processing.

5. Ms. Tetuan stated that she resigned from her position with SinfoniaRx on May 24, 2019, and was not aware that the pharmacy had been granted a license on June 28, 2019. She updated her address and employment online on June 6, 2019. When logging in online to update her home address with the Board on October 20, 2019, she learned that the pharmacy had received its license and that she was listed as the PIC. She was under the impression that SinfoniaRx had not yet submitted the application when she resigned and that they had designated another pharmacist for a new application.

6. On November 27, 2019, Deputy Director LaRue emailed Christa Tetuan and asked her if she notified Saul Ortega once she noticed that she was still listed as the PIC of SinfoniaRx. Tetuan's response was that she contacted Mr. Ortega by text and phone call on October 21, 2019 and informed him that he needed to change the PIC for the pharmacy.

7. Deputy Director LaRue does not believe that the pharmacy would have designated a new PIC until their license came up for renewal in June 2020 without the text and phone call from Christa Tetuan.

8. Respondent, SinfoniaRx, Inc., (License No. 99-8494), neither admits nor denies guilt regarding Count 1 and Count 2, as set forth in the Complaint filed herein.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S.§§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondent has violated OAC 535:15-3-9. Non-resident pharmacies.

(b) Licensing requirements. A non-resident pharmacy shall:

(6) submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident's pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC, as set forth in Count 1 of the Complaint.

4. Respondent has violated OAC 535:25-7-3. Registrant conduct.

(a) Registrants shall conduct business in conformity with all federal, state and municipal laws at all times, as set forth in Count 2 of the Complaint.

5. Count 3 of the Complaint is hereby dismissed by agreement of the parties.

6. Pursuant to Title 59 O.S. §353.7 (12); any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, is subject to the Board's authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

7. Based on the above Agreed Findings of Fact and Agreed Conclusions of Law, the Board finds by clear and convincing evidence that the Respondent is subject to disciplinary action pursuant to Title 59 O.S. §§ 353.7 and 353.26.

AGREED ORDER

1. Respondent is hereby fined Three Thousand and no/00 Dollars ($3,000.00) for the violations alleged in Count 1, plus Two Thousand and no/00 Dollars ($2,000.00) for the violations alleged in Count 2, for a total fine of Five Thousand and no/00 Dollars ($5,000.00). This fine is payable on January 15, 2020.

2. Respondent is prohibited from providing any pharmacist or pharmacy related services to any person located within the State of Oklahoma until the ownership of the Respondent pharmacy employs an Oklahoma licensed pharmacist as a PIC regarding the Respondent's

patients/clients located within the State of Oklahoma.

3. Failure of Respondent to abide by any of the terms of this Agreed Order could result in further disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules. Respondent's Oklahoma Pharmacy license will remain in good standing pursuant to the terms of this Agreed Order.

4. The terms of this Agreed Order are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Agreed Order nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought. Further, the Respondent hereby waives any and all rights he/she or anyone on his/her behalf may have to appeal this Agreed Order to any court or to request a rehearing of this matter pursuant to any provision of Title 75 O.S. § 317.

5. Respondent, together with his/her heirs, assigns, and his/her attorneys, does hereby waive and release the Board, its members and any of its employees, agents, and attorneys of, or from, any liability, claim, actions, causes of actions, fees, costs, and expenses including any claims arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this Agreed Order, or from the negotiation or execution of this Agreed Order. The parties acknowledge that this paragraph is severable from the remaining portions of this Agreed Order in that it survives in perpetuity even in the event that any court of law deems this Agreed Order or any portion thereof void or unenforceable.

6. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

The Board approves this Agreed Order on a Roll Call vote of _____.

Gregg Adams, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 15 day of January, 2020.

Notary Public

My Commission Expires:

(SEAL)

MARJAN FARDADFARD NOTARY PUBLIC # 19009232 EXP. 09/11/23 STATE OF OKLAHOMA

I, Rose Martin, Pharm. D., Chief Operating Officer of SinfoniaRx, Inc., have read the above Agreed Findings of Fact, Conclusions of Law and Agreed Order. I understand the Respondent has the right to be represented by an attorney during these proceedings and do hereby waive that right and intend to proceed without an attorney. I understand that Respondent will be waiving certain rights accorded under Oklahoma Law. I also understand that Respondent must comply with the terms and conditions of the Agreed Order or further discipline will be imposed on Respondent. On behalf of SinfoniaRx, Inc., I agree to the above Agreed Order.

Dated this 14 day of January, 2020.

Rose Martin, Pharm. D.,
Chief Operating Officer
SinfoniaRx, Inc., Respondent

State of Arizona)
) ss.
County of Pima)

Subscribed and sworn before me on this the 14 day of January, 2020.

Notary Public

My Commission Expires:

(SEAL)

NISSI A. SIMMONS
Notary Public -- Arizona
Pima County
My Comm. Expires Mar 10, 2022

11D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH***_____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Pyramids Infusion Center

Physical Address: 500 N Kobayashi Rd., Suite D, Webster, TX 77598

Mailing Address: 2656 South Loop West, Suite 255

City: Houston State: TX Zip Code: 77054

Telephone: 832.932.5836 Fax: 832.832.5936

✓ Toll Free Number: 855.889.9965 (Required per NAC 639.708)

E-mail: specialty@pyramidspharmacy.com Website: www.pyramidspharmacy.com

Managing Pharmacist: Rawad Nasr License Number: 64582

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☑	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☑	☐ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☑	☐ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Osama Kasseb
Print Name of Authorized Person

03/19/2021
Date

Board Use Only Date Processed:_____ Amount: 500
Check# 1660034960

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Texas

Parent Company if any: Sphinx Pharmacy Group Webster Inc. DBA Pyramids Infusion Center

Mailing Address: 2656 South Loop West, Ste. 255

City: Houston State: TX Zip: 77054

Telephone: 713.360.6854 Fax: 713.513.5358

Contact Person: Islam Abdelhamid / Pharmacy Development Manager

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Osama Kasseb, Crescent Cove Dr., Pearland, TX 77584
Name Address

b) Rasha Elmahdy, Ivory Creek Dr., Pearlnd, TX 77584
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1000

3) What was the price paid per share? No Par Value

4) What date did the corporation actually receive the cash assets? 07/06/2012

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8.30 am 5.00 pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Osama Kasseb

Responsible Person of Sphinx Pharmacy Group Webster Inc. DBA Pyramids Infusion Center hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Osama Kasseb
Print Name of Authorized Person

03/19/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Texas)
) ss.
Harris COUNTY)

I, Osama Kasseb, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner for Pyramids Infusion Center (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Osama Kasseb, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Type text here
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
19th day of March, 2021.

Veronica Ogun
NOTARY PUBLIC

VERONICA OGUN
Notary Public, State of Texas
Comm. Expires 03-07-2023
Notary ID 130471069

List of Officers & Directors

Name	Title or Office Held
Osama Kasseb	COO
Rasha ElMahdy	Owner

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

Ruth R. Hughs 2464
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Sphinx Pharmacy Group Webster Inc (file number 801621940), a Domestic For-Profit Corporation, was filed in this office on July 06, 2012.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 17, 2021.

Ruth R. Hughs
Secretary of State

TEXAS STATE BOARD OF PHARMACY

Re:	Pyramids Infusion Center
Address:	500 North Kobayashi Road, Suite D Webster, Texas 77598
License No.:	29199
Date Issued:	April 10, 2014
Licensure Status:	Active
Expiration Date:	April 30, 2022
Type of Pharmacy:	Community Sterile Compounding
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Pyramids Infusion Center (Texas Pharmacy License #29199) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Megan G. Holloway

Megan G. Holloway
Deputy General Counsel
Texas State Board of Pharmacy

March 25, 2021
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **29199** Expiration Date: **4/30/2022**

Balances: **0**

PYRAMIDS INFUSION CENTER
500 N KOBAYASHI RD STE D
WEBSTER TX 77598

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

11E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☒ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: UCSD Home Infusion Pharmacy

Physical Address: 9610 Ridgehaven Court STE A, San Diego, CA 92123

Mailing Address: 9610 Ridgehaven Court STE A,

City: San Diego, State: CA Zip Code: 92123

Telephone: 619-543-7453 Fax: 619-543-2001

Toll Free Number: 855 388 8022 (Required per NAC 639.708)

E-mail: jbailly@health.ucsd.edu Website: health.ucsd.edu

Managing Pharmacist: Binh Ngo License Number: CA 55606: Exp. 02/28/2022

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☒	☐ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☐	☑ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☒	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☐	☑ Other: _____	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☐	☑ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jason Bailly
Print Name of Authorized Person

2/8/2021
Date

Board Use Only Date Processed:_____ Amount: 500

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: California (written into the CA State Constitution 100 years ago)

Parent Company if any: Please see attached Org chart

Mailing Address: 9610 Ridgehaven Ct Suite A

City: San Diego State: CA Zip: 92123

Telephone: 6195437453 Fax: 6195432001

Contact Person: Jason Bailly

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Not Applicable
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. Not Applicable

3) What was the price paid per share? Not Applicable

4) What date did the corporation actually receive the cash assets? Not Applicable

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: Not Applicable %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:00 am 5:00 pm Saturday N/A am _____ pm

Sunday N/A am _____ pm 24 Hours On call 24/7 at 855 388 8022

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: Not Applicable

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

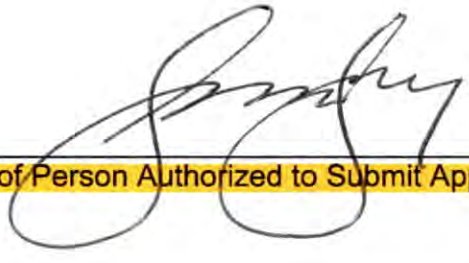
I, Jason Bailly

Responsible Person of UCSD Home Infusion Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Jason Bailly
Print Name of Authorized Person

2/8/2021
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF California)
) ss.
San Diego COUNTY)

I, Jason Bailly, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Responsible Person for UCSD Home Infusion Pharmacy (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Jason Bailly, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
03 day of February, 2021.

NOTARY PUBLIC

ROBYN MARIE MEEHAN-KELLEY
Commission No. 2257963
NOTARY PUBLIC-CALIFORNIA
SAN DIEGO COUNTY
My Comm. Expires OCTOBER 11, 2022

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHE 37284

NAME: UCSD HOME INFUSION PHARMACY

LICENSE TYPE: PHARMACY (GOVERNMENT OWNED COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS
9610 RIDGEHAVEN COURT SUITE A
SAN DIEGO CA 92123
SAN DIEGO COUNTY

ISSUANCE DATE
AUGUST 23, 1991

EXPIRATION DATE
JULY 1, 2021

CURRENT DATE / TIME
FEBRUARY 5, 2021
2:41:04 PM

LICENSE RELATIONSHIPS

NAME: UCSD HOME INFUSION PHARMACY

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY (GOVERNMENT OWNED)

LICENSE NUMBER: 100098 **PRIMARY STATUS:** CLEAR

ADDRESS :
9610 RIDGEHAVEN COURT
SAN DIEGO CA 92123
SAN DIEGO COUNTY

NAME: NGO, BINH Q

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 55606 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 11, 2021

UCSD Home Infusion Pharmacy
Attn: Jason Bailly
9610 Ridgehaven Court Suite A
San Diego, CA 92123

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: UCSD HOME INFUSION PHARMACY

License Type: PHARMACY

License Number: PHE 37284

Status: ACTIVE

Issue Date: 08/23/1991

Expiration Date: 07/01/2021

Address of Record: 9610 RIDGEHAVEN COURT SUITE A SAN DIEGO, CA 92123

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3141
Pharmacy.PublicRecords@dca.ca.gov

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHE 37284
RECEIPT NO. 31446462

VALID UNTIL JULY 01, 2021

UCSD HOME INFUSION PHARMACY
9610 RIDGEHAVEN COURT SUITE A
SAN DIEGO CA 92123

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the fee here shown is issued at the address shown, and is subject to the laws and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days after there is a change of ownership, location, corporate officer, clerk, or pharmacist-in-charge. Failure to report these changes may result in penalties or cancellation of this permit. This permit is valid only at the address shown.

04/24/20
04/24/20 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHE (09/30/19) PHE

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHE 37284

NAME: UCSD HOME INFUSION PHARMACY

LICENSE TYPE: PHARMACY (GOVERNMENT OWNED COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

9610 RIDGEHAVEN COURT SUITE A
SAN DIEGO CA 92123
SAN DIEGO COUNTY

ISSUANCE DATE

AUGUST 23, 1991

EXPIRATION DATE

JULY 1, 2021

CURRENT DATE / TIME

MARCH 15, 2021
1:19:09 PM

LICENSE RELATIONSHIPS

NAME: UCSD HOME INFUSION PHARMACY

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY (GOVERNMENT OWNED)

LICENSE NUMBER: 100098 **PRIMARY STATUS:** CLEAR

ADDRESS :
9610 RIDGEHAVEN COURT
SAN DIEGO CA 92123
SAN DIEGO COUNTY

NAME: NGO, BINH Q

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 55606 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

Nevada State Board of Pharmacy

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

March 26, 2021

VIA CERTIFIED U.S. MAIL

Binh Ngo, Pharm.D.
Pharmacy Manager, Pharmacy Home Infusion Service
UC San Diego Health
9610 Ridgehaven Ct - Ste A
San Diego, CA 92123

Re: CEASE and DESIST/CITATION/FINE: Unlicensed Pharmacy Practice (Case 21-041-PH-S)

Dear Mr. Ngo:

The Nevada State Board of Pharmacy (Board) is in receipt of your March 16th correspondence self-reporting that UC San Diego Health Pharmacy Home Infusion Service engaged in unlicensed pharmacy practice in Nevada by shipping drug prescriptions to patients in the State. This constitutes a violation of State law, including, without limitation, NRS 639.2328 and NRS 639.285.

UC San Diego Health Pharmacy Home Infusion Service is hereby ordered pursuant to NRS 639.2895(1) to immediately CEASE and DESIST shipping drug prescriptions to Nevada patients until licensed pursuant to State law. This notice shall serve as a CITATION pursuant to NRS 639.2895(2) for unlicensed activity. The Board has assessed UC San Diego Health Pharmacy Home Infusion Service an administrative fine of five thousand dollars ($5,000.00) pursuant to NRS 639.2895(3).

UC San Diego Health Pharmacy Home Infusion Service must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check, certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

UC San Diego Health Pharmacy Home Infusion Service has the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this letter. *See* NRS 639.2895(2). Please be aware that the forgoing does not preclude the filing of administrative or criminal charges. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

9171 9690 0935 0252 0543 22

UC San Diego Health

UC San Diego Health
Specialty Infusion Pharmacy
9610 Ridgehaven Ct Suite A
San Diego, CA 92123
T: 619 543 5231
F: 619 543 2001
health.ucsd.edu

06/08/2021

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521

To Whom It May Concern:

Please find the requested documentation enclosed in this correspondence, to satisfy the Nevada Board of Pharmacy request to complete our out of state licensure application.

Please let me know if I can provide any more required information.

Professionally,

Binh Ngo, PharmD
Pharmacist in Charge

Binh Ngo, PharmD
Pharmacist in Charge
Specialty Infusion Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 11, 2021

UCSD Home Infusion Pharmacy
Attn: Jason Bailly
9610 Ridgehaven Court Suite A
San Diego, CA 92123

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: UCSD HOME INFUSION PHARMACY

License Type: PHARMACY

License Number: PHE 37284

Status: ACTIVE

Issue Date: 08/23/1991

Expiration Date: 07/01/2021

Address of Record: 9610 RIDGEHAVEN COURT SUITE A SAN DIEGO, CA 92123

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3141
Pharmacy.PublicRecords@dca.ca.gov

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 5/20/2021 Inspector: Ben Rustia

Firm: UCSD HOME INFUSION PHARMACY Phone: (619) 543-5231

Address: 9610 RIDGEHAVEN COURT SUITE A City: SAN DIEGO Zip: 92123

Ownership: CORPORATION

Permit #: PHE37284 LSE100098 Permit Exp: 7/1/2021 DEA#: BU2844531 DEA Exp: 5/31/2024

Date of Self Assessment Form: 4/29/2019 Other Permit #: N/A Date of DEA Inventory: 4/19/2019

Hours M-F: 9AM-5PM Hours Saturday CLOESED Hours Sunday: CLOSED

PIC BINH Q NGO RPH55606 Administrator

RPH Consultant

Staff	RPH Name:	License #:
	LESLIE E KIM	RPH67592
	RONNIE J DELMONTE	RPH74914
	KATHRYN V BARRY	RPH44502
	SHIVANI S BHATTACHARYA	RPH68950
	GIOVANNI J LAIRD	RPH66395
	JANE L CHEN	RPH65936
	JOHN B WANG	RPH81206
	THU-VAN T LE	RPH66396
	ELIZABETH L TYSON	RPH40488
	CELESTE V MANGUNE	RPH63352
	JASON R BAILLY	RPH60771

Staff Name:	License #:
ALEXANDRA ISLAS	TCH79105
ALEIE O BROSAS	TCH43896
DONGHWAN KIM	TCH126360
LIZABETH LEOS	TCH42057
LYDIA TORRES	TCH13681
MARIA C MEDEL	TCH36015
MELISSA SANDER	TCH41900
MIKE D MCQUEARY	TCH79060
MUSTAFA K KARAMALLAH	TCH153233
NATALIA DIVINO	TCH62223
PRISCILLA M RODRIGUEZ	TCH127289
SAMUEL O'NEAL JR	TCH13849
SANDRA VILLEGAS	TCH23385
SEAN M LARSON	TCH163730
SELINA D BARTON	TCH70384
SENETHAVISOK TRAN	TCH94631
SHELLY BALDEMOR	TCH52483
WILLIAM MACIEL	TCH117268

Inspector Remarks:

Sterile compounding inspection for LSE 100098 conducted by Inspector Emerald Foster on 4/27/2021.

The pharmacy inspection conducted today primarily focuses on the outpatient pharmacy.
Closed door pharmacy primarily services UCSD Health patients.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Pharmacy Self-Assessment and Compounding Self-Assessment: reviewed
Policies and Procedures: In place
Quality Assurance; Impaired employee/Theft and diversion; Technician Job Description; Interpretive services
Reviewed recent DEA 222 Forms – endorsed; C II invoices –filed separately; POA – in place;
CIII-V daily printout electronically stored and can be printed on demand. Pharmacists signature log attesting to the refilling of controlled substance prescriptions is not in place.
CURES Transmitting
Quarterly reconciliation of Controlled Substances in place, reviewed 2 quarters.
Reviewed CII Prescription Documents, primarily sent electronically.
Opioid Warning Label-Risk of Overdose or Addiction in place
Automated dispensing system - none
Drug acquisition: Amerisource Bergen, Curascript.
Outdates quarantined returned to Inmar
Notice to Consumer and Permits posted in public view.
ID badges worn by technicians
Consultation: provided by the pharmacist by phone prior to the dispensing of the prescription. Consultation documented in prescription profile.
Facility: Secure, orderly, refrigerator and freezer clean, temperatures monitored electronically, sink with hot and cold running water.
RX label – patient centered with physical description of drug
Interpretative services: Board language poster and telephonic
Pharmacy receives email notification from the Board.
Computer software capable of translating direction for use in the five required languages, Spanish, Korean, Russian, Chinese, and Vietnamese.
Pharmacist does not provide hormonal contraceptive, emergency contraceptive, naloxone per protocol.

Educational topics Discussed:

- CE requirements for renewal of pharmacist license. Board provides webinars and DEA trainings.

DISCUSSION:

1. Biennial inventory has to be completed within 2 years from the last inventory. Last inventory completed on 4/19/2019. PIC to completed the biennial inventory of CS and provide a copy of the inventory to Inspector Rustia.
2. Shelves dusty requires cleaning.
3. CIII-V daily printout electronically stored and can be printed on demand. Pharmacists signature log attesting to the refilling of controlled substance prescriptions is not in place.
4. Reminder of the requirement for Pharmacist, Interns and Pharmacy technicians to submit email address to Board.
5. Reminder Pharmacy Self-Assessment and Compounding Self-Assessment is due to be completed by 7/1/2021. Rev 2021 is currently available in the Board Website.

COMPLAINT INVESTIGATION: 2020 91284
Here to investigate and obtain documents related to the complaint.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed, understand and received a copy of this form.

Pharmacist (sign) _____

Pharmacist (print) Binh Ngo

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 5/20/2021 Permit #: PHE37284

Time of Day: 10:26 AM

Name as shown on permit: **UCSD HOME INFUSION PHARMACY**

Address: 9610 RIDGEHAVEN COURT SUITE A City: SAN DIEGO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CFR 1306.22(f)(3)	Refilling of prescriptions.. As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions: Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill. In that, the pharmacy does not maintain a daily printout of the CSs refilled, and does not maintain a signature log of the pharmacist attesting to the fact that the refill information entered into the computrer that day has been reviewed by himand is correct as shown.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) R. Rustia Print Name Binh Ngo

Date 5/20/2021 Title Pharmacy Manager

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ *New Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH*** _____

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☒ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Northmark Pharmacy

Physical Address: 1945 CEI Drive

Mailing Address: (SAME)

City: Cincinnati State: OH Zip Code: 45242

Telephone: 513-569-3334 Fax: 513-569-3902

Toll Free Number: 1-800-544-5133 (Required per NAC 639.708)

E-mail: dchachare@ Website: northmarkpharmacy.com

Managing Pharmacist: Deepali Chachare License Number: 03230717

TYPE OF PHARMACY	AND	SERVICES PROVIDED
Yes/No		Yes/No
☒ Retail		☐ ☒ Off-site Cognitive Services
☐ ☒ Hospital (# beds_____)		☐ ☒ Parenteral **
☐ ☒ Internet		☐ ☒ Parenteral (outpatient)
☐ ☒ Nuclear		☐ ☒ Outpatient/Discharge
☐ ☒ Ambulatory Surgery Center		☒ ☐ Mail Service
☐ ☒ Community		☐ ☒ Long Term Care
☒ ☐ Other: Mail Order		☒ ☐ Sterile Compounding **
		☐ ☒ Non Sterile Compounding
All boxes must be checked		☒ ☐ Mail Service Sterile Compounding **
For the application to be complete		☐ ☒ Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Deepali Chachare — Print Name of Authorized Person

05/19/2024 — Date

Board Use Only Date Processed:_____ Amount: 500 Check # 5071

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General ✓ Limited _____

Partnership Name: CEI Physicians, P.S.C., LLC

Mailing Address: 1945 CEI Drive

City: Cincinnati State: OH Zip Code: 45242

Telephone Number: 513-569-3334 Fax Number: 513-569-3902

Contact Person: Deepali Chachare

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
CEI Physicians, P.S.C, LLC	G	100%

List names of 4 largest partners and percentage of ownership:

Name: N/A %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: N/A %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8 am 4 pm Saturday 8 am 1 pm

Sunday Closed am _____ pm 24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

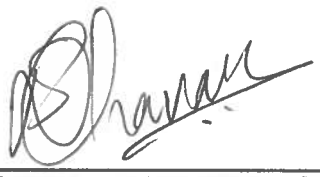
I, Deepali Chachare

Responsible Person of Northmark Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Deepali Chachare

Print Name of Authorized Person

05/19/2021

Date

STATE OF OHIO
BOARD OF PHARMACY

VERIFICATION OF LICENSURE

BUSINESS NAME:	NORTHMARK PHARMACY
LOCATION:	1945 CEI DRIVE BLUE ASH, OH 45242
LICENSE NUMBER:	022247900
TYPE OF LICENSE:	Terminal - Pharmacy - Category 3
ORIGINAL LICENSURE DATE:	November 26, 2012
EXPIRATION DATE:	July 1, 2021
CURRENT LICENSE STATUS:	Active
CURRENT LICENSE SUB STATUS:	N/A
BOARD ACTION:	No (If Board Action is "Yes", you may find more information at elicense.ohio.gov)
DATE OF VERIFICATION:	5/13/2021

Karrie Southard

Karrie Southard
Director of Licensing
State of Ohio Board of Pharmacy

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

From: AOL ronwferguson@cs.com
Subject: GS
Date: May 17, 2021 at 11:03:20 PM
To: AOL ronwferguson@cs.com

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show CEI PHYSICIANS, P.S.C., LLC, an Ohio For Profit Limited Liability Company, Registration Number 951096, was organized within the State of Ohio on August 23, 1996, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 17th day of May, A.D. 2021.

Ohio Secretary of State

Validation Number: 202113706702

2493

Ohio | eLicense Ohio Professional Licensure

License Look Up

4/6/2021 3:42 PM

NORTHMARK PHARMACY

Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Number	022247900
License Issue Date	11/26/2012
License Expiration Date	07/01/2021
License Effective Date	04/01/2019
Street Address	1945 CEI DRIVE
City	BLUE ASH
State	OH
Zipcode	45242
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
	03230717	Active	Tue Apr 09 00:00:00 GMT 2013	

Current date & time: **4/6/2021 3:42 PM**

12B

RECEIVED 9-22-2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy or* ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH_____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,8*
☐ *Partnership - Pages 1,2,6,8*
☑ *Non Publicly Traded Corporation – Pages 1,2,4,8*
☐ *Sole Owner – Pages 1,2,7,8*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Soleo Health Inc.

Physical Address: 6190 Shamrock Ct., Suite 100, Dublin, OH 43016

Mailing Address: 11 Trafalgar Square, Suite 101

City: Nashua State: NH Zip Code: 03063

Telephone: 614-467-8200 Fax: 614-467-8300

Toll Free Number: 844-467-8200 (Required per NAC 639.708)

E-mail: licensure@soleohealth.com Website: www.soleohealth.com

Managing Pharmacist: Jason Doenges License Number: 03122815

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds_____)	☑	☐ Parenteral **
☐	☑ Internet	☐	☑ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☑	☐ Other: Specialty Pharmacy and Infusion Services	☑	☐ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☑	☐ Mail Service Sterile Compounding **
	For the application to be complete	☑	☐ Other Services: Specialty Pharmacy and Infusion Services

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

John Ginzler, CFO
Print Name of Authorized Person

Aug 27, 2020
Date

Board Use Only	Date Processed:	Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Soleo Health Inc.

Mailing Address: 11 Trafalgar Square, Suite 101

City: Nashua State: NH Zip: 03063

Telephone: 833-765-3648 Fax: 603-718-3824

Contact Person: Holly Anderson

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) _____
Name Address

b) NA
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 8:30 am 5:00 pm Saturday on call am 24/7 pm

Sunday on call am 24/7 pm 24 Hours on call 24/7

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, John Ginzler

Responsible Person of Soleo Health Inc.

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

John Ginzler, CFO
Print Name of Authorized Person

Aug 27, 2020
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF New Hampshire)
) ss.
Hillsborough COUNTY)

I, John Ginzler, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CFO for Soleo Health Inc. (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, John Ginzler, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Rosa Ginzler
Name

SUBSCRIBED AND SWORN TO before me, a notary public this 17th day of August, 2020.

ROSALINDA B. GINZLER
STATE OF
MY COMMISSION EXPIRES OCTOBER 5, 2021
NEW HAMPSHIRE
NOTARY PUBLIC

NOTARY PUBLIC

SOLEO HEALTH
Innovators in Specialty Infusion

PRIVILEGED AND CONFIDENTIAL INFORMATION

Corporate Officers

Andrew C. Walk - Chief Executive Officer
2801 Network Blvd, Suite 505
Frisco, TX 75034
(833)765-3648
0% owned

John Ginzler - Chief Financial Officer
11 Trafalgar Square, Suite 101
Nashua, NH 03063
(833)765-3648
0% owned

Ron Lindahl – Chief Operating Officer
2801 Network Blvd, Suite 505
Frisco, TX 75034
(833)765-3648
0% owned

Craig Vollmer – Chief Commercial Officer
2801 Network Blvd, Suite 505
Frisco, TX 75034
(833)765-3648
0% owned

Corporate Directors

Paul McConnell – Chairman of the Board
2801 Network Blvd, Suite 505
Frisco, TX 75034
(833)765-3648
0% owned

Brian Schwartz - Board Member
1450 Brickell Avenue 31st Floor
Miami, FL 33131
(305) 379-2322
0% owned

Eric Rogoff - Board Member
600 Lexington Ave 35th Floor
New York, NY 10022
(617) 412-2700
0% owned

Miriam Rafiqi - Board Member
1450 Brickell Avenue 31st Floor
Miami, FL 33131
(212) 506-0500
0% owned

Registered Pharmacist

Jason Doenges, RPh
0% owned

Corporate Shareholders

Soleo Health Inc. – 100% owned
Soleo Health Holdings, Inc. – owns 100% of Soleo Health Inc.
Brickell Bay Acquisition Corp. –owns 100% of Soleo Health Holdings, Inc.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SOLEO HEALTH INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF JUNE, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SOLEO HEALTH INC." WAS INCORPORATED ON THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2014.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5486590 8300

SR# 20212306140

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203336563

Date: 06-01-21

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2023.

SOLEO HEALTH INC.

6190 Shamrock Ct Ste 100

Dublin, OH 43016-1279

License Number: 022403050

Terminal - Pharmacy - Category 3

Expiration Date: March 31, 2023

CLASS: Terminal - Pharmacy - Category 3
BUSINESS TYPE: FL – Fluid Therapy

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
JASON S DOENGES	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Ohio | eLicense Ohio Professional Licensure

License Look Up

6/1/2021 5:47 PM

SOLEO HEALTH INC.

Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Number	022403050
License Issue Date	04/03/2014
License Expiration Date	03/31/2023
License Effective Date	04/01/2021
Street Address	6190 Shamrock Ct Ste 100
City	Dublin
State	OH
Zipcode	43016-1279
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
JASON DOENGES	03122815	Active	Tue Apr 21 00:00:00 GMT 2020	
Aaron Webb	APP-000461922	Pending	Mon May 03 00:00:00 GMT 2021	

Current date & time: **6/1/2021 5:47 PM**

2503

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

13

13A

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change ☐ Name Change ☐ Location Change

(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6

☒ Non Publicly Traded Corporation – Pages 1,2,3,5a,5b ☐ Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: CRANIAL TECHNOLOGIES, INC.

Physical Address: 8285 W. ARBY AVE. #235 LAS VEGAS NV 89113

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 1395 W. AUTO DRIVE

City: TEMPE State: AZ Zip Code: 85284

Telephone: 844-447-5894 Fax: 844.447.5895

E-mail: CMOLSBERRY@CRANIALTECH.COM Website: WWW.CRANIALTECH.COM

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

TEMPORARY HOURS UNTIL FULL TIME:

Mon: 9AM to 6AM Tue: 7:30 AM to 4:30PM Wed: CLOSED to Thu: CLOSED to

Fri: CLOSED to Sat: CLOSED to Sun: CLOSED to Holidays: CLOSED to

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Kelly Johnson

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases** ☐ Assistive Equipment

☐ Respiratory Equipment** ☐ Parenteral and Enteral Equipment**

☐ Life-sustaining equipment** ☒ Orthotics and Prosethics

☐ Diabetic Supplies Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name: N/A Telephone: _____

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

SEE ATTACHED ADDENDUM

1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒

3) Are any of the owners health professionals? If yes, please check the box and list name.

☐ Practitioner	Name: N/A
☐ Advanced Practitioner of Nursing	Name:
☐ Physician's Assistant	Name:
☐ Physical Therapist	Name:
☐ Occupational Therapist	Name:
☐ Registered Nurse	Name:
☐ Respiratory Therapist	Name:

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Darren Wight

Original Signature of Person Authorized to Submit Application, no copies or stamps

DARREN WIGHT

Print Name of Authorized Person

5/14/24

Date

Board Use Only	Received:	Amount: 500 Check # 79553

APPLICATION FOR NEVADA MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: ARIZONA

Parent Company if any: CRANIAL TECHNOLOGIES INTERMEDIATE HOLDINGS INC.

Corporation Name: CRANIAL TECHNOLOGIES, INC.

Mailing Address: 1395 W. AUTO DR.

City: TEMPE State: Zip: AZ 85284 Telephone: 480 403 6374

Fax: 8447475895 Contact Person: CRAYN MOLSBERRY

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A - 100% OWNED BY CORPORATION
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses.*

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

Addendum to:
Application for Nevada Medical Device, Equipment & Gases (MDEG)
List of Medicare and Medicaid provider numbers registered to the business or its owner:

Clinic Location:
Cranial Technologies Inc.
8285 W Arby Ave Ste 235 Las Vegas, NV 89113-2235

NOTE: The following list of clinics are enrolled in their state's Medicaid under their service location NPI. Locations with a PTAN are also enrolled with Medicare:

Medicaid ID/NPI	Medicare ID/PTAN	State	Address
1841857596		AZ	7330 N 99th Ave, Ste 225, Glendale, AZ 85307
1740723907		AZ	1500 S Dobson Rd, Ste 315, Mesa, AZ 85202
1336264944		AZ	1920 E Cambridge Ave, Bldg E, Ste 205, Phoenix, AZ 85006
1992362370		AZ	6373 E Tanque Verde Rd, Ste 140, Tucson, AZ 85715
1407468416		CA	488 E Valley Pkwy Ste 207 Escondido, CA 92025
1376183848	675320021	CA	30 River Park Place West, Ste 280, Fresno, CA 93720
1740812387	675320023	CA	1040 Elm Ave, Ste 304, Long Beach, CA 90813
1669759486		CA	11620 Wilshire Blvd, Ste 200, Los Angeles, CA 90025
1114567765		CA	515 South Dr,Ste 23, Mountain View, CA 94040
1629629845	675320009	CA	3300 Webster St, Ste 1109, Oakland, CA 94609
1326349630		CA	1010 W La Veta Ave, Ste 510, Orange, CA 92868
1588842330		CA	200 E Del Mar Blvd, Ste 104 Pasadena, CA 91105
1891211942		CA	4244 Riverwalk Pkwy, Ste 180, Riverside, CA 92505
1972147916	675320020	CA	2825 J St, Ste 325, Sacramento, CA 95816
1568587160		CA	8010 Frost St, Ste 500, San Diego, CA 92123
1629624127	675320022	CA	1100 Van Ness Ave, Ste 1000, San Francisco, CA 94109
1942766290		CO	7800 E Orchard Rd, Ste 120, Greenwood Village, CO 80111
1043783145		CO	9351 Grant St, Ste 650, Thornton, CO 80229
1922123538		CT	1343 Boston Post Rd, Ste 102, Madison, CT 06443
1427490002		FL	1905 Clint Moore Rd, Ste 301, Boca Raton, FL 33496
1295367837		FL	1300 Riverplace Blvd, Ste 100, Jacksonville, FL 32207
1649396789		FL	7000 SW 62nd Ave Ste 400-A, South Miami, FL 33143
1093183824		FL	2902 N Orange Ave, Ste C, Orlando, FL 32804
1720442981		FL	14497 N Dale Mabry Hwy, Ste 125-N Tampa, FL 33618
1174999858		GA	5901 Peachtree Dunwoody Rd, Ste A-155, Atlanta, GA 30328
1861905325		GA	3235 Satellite Blvd, Bldg 400, Ste 150, Duluth, GA 30096
1013420363		GA	709 Canton Rd NE, Ste 220, Marietta, GA 30060
1073077848		GA	239 Village Center Pkwy, Ste 230, Stockbridge, GA 30281
1235541574		IL	1333 W Belmont Ave, Ste 340, Chicago, IL 60657
1861918914		IL	1600 N Randall Rd, Ste 145 Elgin, IL 60123
1265557888		IL	720 E Butterfield Rd, Ste 180, Lombard, IL 60148
1760047583		IL	13500 Circle Dr, Ste 202, Orland Park, IL 60462

1134244742		IL	4709 Golf Rd, Tower 2, Ste 510, Skokie, IL 60076
1710465166		IN	10603 N Meridian St, Ste 120, Indianapolis, IN 46290
1508260910	675320016	MD	5450 Knoll North Drive, Suite 340 Columbia, MD 21045
1205338860	675320018	MD	10750 Columbia Pike, Ste 100, Silver Spring, MD 20901
1699264192		MI	25500 Meadowbrook Rd, Ste 280, Novi, MI 48375
1215400312		MO	4801 Main St, Ste 220, Kansas City, MO 64112
In process		MO	755 S New Ballas Rd Ste 140 Saint Louis MO 63141
1427656727	675320025	MO	755 S New Ballas Rd., Ste 140, St. Louis, MO 63141
1063537660	675320004	NC	9300 Harris Corners Pkwy Suite 340 Charlotte NC 28269
1861946584		NC	1000 Southhill Dr, Ste 150, Cary, NC 27513
1659938306		NC	1590 Westbrook Plaza Dr, Ste 101, Winston-Salem, NC 27103
1477185015		NJ	1810 Chapel Ave W, Ste 100, Cherry Hill, NJ 08002
1568885887		NJ	2163 Oak Tree Rd, Ste 104, Edison, NJ 08820
1811012495		NJ	2 University Plaza Dr, Ste 111, Hackensack, NJ 07601
1265081731		NY	1393 Veterans Memorial Hwy, Ste 112N, Hauppauge, NY 11788
1700435278		NY	200 Old Country Rd, Ste 590A, Mineola, NY 11501
1144657024	675320008	NY	495 Central Park Ave, Ste 207, Scarsdale, NY 10583
1962947036		OH	4030 Smith Rd, Ste 105, Cincinnati, OH 45209
1851864953		OH	500 E Main St, Ste 250, Columbus, OH 43215
1205370038		OH	6055 Rockside Woods Blvd, Ste 170, Independence, OH 44131
1174172647		PA	250 Cetronia Rd, Ste 306, Allentown, PA 18104
1730682832		PA	5750 Centre Ave, Ste 100, Pittsburgh, PA 15206
1952878167		TN	1720 West End Ave, Ste 630, Nashville, TN 37203
1578688164		TX	1111 W 34th St, Ste 204, Austin, TX 78705
1689799272		TX	8131 LBJ Freeway, Ste 100, Dallas, TX 75251
1851719918		TX	800 8th Ave, Ste 124, Fort Worth, TX 76104
1922528959		TX	10907 Memorial Hermann Dr, Ste 410, Pearland, TX 77584
In process		TX	8122 Datapoint Dr, Ste 506, San Antonio, TX 78229
1639597792		TX	929 Gessner Rd, Ste 2205, Houston, TX 77024
1396157541		TX	128 Vision Park Blvd, Ste 100 Shenandoah, TX 77384
1841761095		UT	4225 W Lake Park Blvd, Ste 225, West Valley City, UT 84120
1366567950	675320019	VA	3299 Woodburn Rd, Ste 320, Annandale, VA 22003
1376102053		VA	6161 Kempsville Cir, Ste 300, Norfolk, VA 23502
1609433341		VA	8730 Stony Point Pkwy, Ste 140, Richmond, VA 23235
1659873271	675320017	VA	14 Pidgeon Hill Dr, Ste 410, Sterling, VA 20165
1134507429		WI	115 S 84th St., Ste. 410, Milwaukee, WI 53214

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

CRANIAL TECHNOLOGIES, INC.

ACC file number: 06021477

was incorporated under the laws of the State of Arizona on 07/09/1993;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **12/14/2020**

Matthew Neubert, Executive Director

1395 W. Auto Drive • Tempe, AZ 85284
Fax: (844) 447-5895 • Ph: (844) 447-5894

Addendum to:
Application for Nevada Medical Device, Equipment & Gases (MDEG)
List of Officers and Directors:

Clinic Location:
Cranial Technologies Inc.
8285 W Arby Ave Ste 235 Las Vegas, NV 89113-2235

Cranial Technologies Intermediate Holdings, Inc.
131 S Dearborn St Suite 2800
Chicago IL 60603
Percent owned: 100%
Title: Owner / Parent company
Tax ID: 45-4038701
Phone: 312-435-0300

Debra K James
[redacted] E. Kierland Blvd [redacted]
Scottsdale AZ 85254
Percent owned: 0%
Title: CEO
SS [redacted] DOB: [redacted]
Phone: [redacted]

David Cooney
[redacted] S Dearborn St Suite [redacted]
Chicago IL 60603
Percent owned: 0%
Title: Secretary - Board of Directors
SS [redacted] DOB: [redacted]
Phone: [redacted]

Darren J Wight
[redacted] E Comstock Dr
Gilbert AZ 85296
Percent owned: 0%
Title: CFO
SS [redacted] DOB: [redacted]
Phone: [redacted]

Gregory Moerschel
[redacted] S Dearborn St Suite [redacted]
Chicago IL 60603
Percent owned: 0%
Title: Chairman - Board of Directors
SS [redacted] DOB: [redacted]
Phone: [redacted]

Timothy Littlefield
[redacted] E Theia Dr
Mesa AZ 85212
Percent owned: 0%
Title: CTO
SS [redacted] DOB: [redacted]
Phone: [redacted]

Robert Mulfinger
[redacted] B
Nashville TN 37203
Percent owned: 0%
Title: CCO
SS [redacted] DOB: [redacted]
Phone: [redacted]

Amy Culpert
[redacted] Piney Creek Bend
Austin TX 78745
Percent owned: 0%
Title: Regional Clinical Director
SS [redacted] DOB: [redacted]
Phone: [redacted]



CRANTEC-01 ZWALSH

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/13/2021

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

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

PRODUCER	CONTACT NAME: Colleen Sokolowski
Thompson Flanagan Executive Liability Group 626 W. Jackson Blvd. 5th Floor Chicago, IL 60661	PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS: csokolowski@thompsonflanagan.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A : Chubb Custom Insurance Company
INSURED Cranial Technologies, Inc. 1395 W. Auto Drive Tempe, AZ 85284	INSURER B : Federal Insurance Company — 20281
	INSURER C : Chubb Indemnity Insurance Company — 12777
	INSURER D :
	INSURER E :
	INSURER F :

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 10,000,000
	X CLAIMS-MADE ☐ OCCUR			3605-42-40	4/1/2021	4/1/2022	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 10,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 10,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 10,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO			7361-44-84	4/1/2021	4/1/2022	BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 10,000,000
	☐ EXCESS LIAB ☐ CLAIMS-MADE			7989-67-44	4/1/2021	4/1/2022	AGGREGATE	$ 10,000,000
	☐ DED ☐ RETENTION $							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH)	N / A		7183-36-69	4/1/2021	4/1/2022	E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
A	Professional Liabili			3605-42-41	4/1/2021	4/1/2022	Limit	10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
RE: 8285 W Arby Ave Suite 235 Las Vegas NV 89113

CERTIFICATE HOLDER

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

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

NAC 639.694

1. **Each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:**
    a. Be a natural person;
    b. Have a high school diploma or its equivalent;
    c. Have:
        i. At least 1,500 hours of verifiable direct patient-care work experience relating to the products provided by the medical products provider or medical products wholesaler; or
        ii. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
    d. Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
    e. Be approved by the Board.
2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

Please mail this completed application and all other required documents with your MDEG Application to the address indicated above.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/08/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Cranial Technologies Inc MDEG License # (if applicable): _____

Physical Address: 8285 W Arby Avenue Suite 235

City: Las Vegas State: NV Zip: 89113-2235

Mailing Address (if different from physical address): 1395 W Auto Drive

City: Tempe State: AZ Zip: 85284

Telephone: 844-447-5894 Website: www.cranialtech.com

Licensing Company Email: cmolsberry@cranialtech.com

Section 2: Personal Information

First: Kelly Middle: Marie Last: Johnson

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

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

Mailing Address: [redacted] W Auto Drive

City: Tempe State: AZ Zip: 85284

Telephone: [redacted] Email: kjohnson@cranialtech.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
College of Saint Scholastica		08/14 - 05/16	
Address	**City**	**State**	**Zip**
1200 Kenwood Ave	Duluth	MN	55811
Diploma/Degree obtained, if any			
Doctorate of Physical Therapy			

School Name		From - To (MM/YY – MM/YY)	
College of Saint Scholastica		09/79 - 5/83	
Address	**City**	**State**	**Zip**
1200 Kenwood Ave	Duluth	MN	55811
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
W.G. Mather High School			
Address	**City**	**State**	**Zip**
411 Elm Avenue	Munising	MI	49862
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16 to present	[redacted] E Cheery Lynn Road	Phoenix	AZ	85018
02/13 - 6/16	1934 E Siesta Lane	Phoenix	AZ	85024
02/95 - 02/13	5647 E Hartford Avenue	Scottsdale	AZ	85056

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

Business Name N/A - Has a Doctorate of Physical Therapy			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			
Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Kelly Johnson, **certify that as the MDEG Administrator for**

Cranial Technologies, Inc.,

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

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

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

Kelly Johnson
Print Name (First, Last)

Kelly Johnson
Original Signature (electronic, copies or stamps not accepted)

6-21-2021
Date

Board Use Only	Date Received:

13B

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA Medical Device, Equipment & Gases (MDEG)

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New MDEG ☐ Ownership Change ☐ Name Change ☐ Location Change

(Please provide current license number if making changes: MP or MW_____)

☐ Publicly Traded Corporation – Pages 1,2,3,4 ☐ Partnership - Pages 1,2,3,6

☒ Non Publicly Traded Corporation – Pages 1,2,3,5a,5b ☐ Sole Owner – Pages 1,2,3,7

Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION to be completed by all types of ownership

MDEG Name: Patients Choice, LLC

Physical Address: 2350 W Cheyenne Ave #140, North Las Vegas, NV 89032

(This must be a business address, we can not issue a license to a home address)

Mailing Address: 2350 W Cheyenne Ave #140,

City: North Las Vegas, State: NV Zip Code: 89032

Telephone: 847-481-6084 Fax: 866-725-3567

E-mail: del@patientschoicemedical.com Website: www.patientschoicemedical.com

DAYS AND HOURS THAT THE FACILITY WILL BE REGULARLY OPERATING

Mon: 9:00 am to 3:00 pm Tue: 9:00 am to 3:00 pm Wed: 9:00 to 3:00 Thu: 9:00 am to 3:00 pm

Fri: 9:00 am to 3:00 pm Sat: N/A to Sun: N/A to Holidays: N/A to

MDEG ADMINISTRATOR INFORMATION (MDEG administrator application required)

Name: Daniel Scott Graves Jr (Alias: "DeeJay")

TYPE OF MDEG PRODUCTS THAT WILL BE SOLD (CHECK ALL APPLICABLE)

☐ Medical Gases**
☐ Respiratory Equipment**
☐ Life-sustaining equipment**
☐ Diabetic Supplies
☒ Assistive Equipment
☐ Parenteral and Enteral Equipment**
☐ Orthotics and Prosethics
Other: _____

**If providing these types of services you are required to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact. Name:_____ Telephone: _____

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

List all Medicare and Medicaid provider numbers registered to the business or its owner:

5928030001		
1538373998		

1) Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

2) Are you or have you in the last year been associated with any person, business or health care entity in which MDEG products were sold, dispensed or distributed? Yes ☐ No ☒

3) Are any of the owners health professionals? If yes, please check the box and list name.

☐ Practitioner	Name: Not Applicable
☐ Advanced Practitioner of Nursing	Name:
☐ Physician's Assistant	Name:
☐ Physical Therapist	Name:
☐ Occupational Therapist	Name:
☐ Registered Nurse	Name:
☐ Respiratory Therapist	Name:

Practicing licensed health care professionals cannot obtain a license per NAC 639.6943.

APPLICATION FOR NEVADA MDEG LICENSE

This page must be submitted for all types of ownership.

1) Has the corporation, any owner, shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to questions 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized MDEG provider or wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Daniel Scott Graves Jr.
Print Name of Authorized Person

3/9/2021
Date

Board Use Only	Received:	Amount: 500 fee paid already

APPLICATION FOR NEVADA MDEG LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: Not Applicable

Corporation Name: Patients Choice, LLC

Mailing Address: 2350 West Cheyenne Ave. Auite #140

City: North Las Vegas State: Nevada Zip: 89032 Telephone: 847-481-6084

Fax: 866-725-3567 Contact Person: Daniel Scott Graves Jr. "DeeJay"

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Delbert Rinquest, CEO / Founder — 45 W Farm Springs LN, Midway, UT 84049
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

N/A

APPLICATION TO BE THE MDEG ADMINISTRATOR

Person who runs the facility on a daily basis

Date 3/9/2021

Each MDEG shall employ an administrator at all times. The administrator must be:

1. A natural person.
2. Have a high school diploma or its equivalent.
3. Have: a) At least 1500 hours of verifiable work experience relating to the products provided be the medical products provider or medical products wholesaler or b) An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care.
4. Be employed be the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week and
5. Be approved by the board.
6. The administrator shall ensure that that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business dates after the beginning of the employment.

A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

GENERAL INSTRUCTIONS

Type or print an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner.

All applicants are advised that this application to be a MDEG administrator is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Assistive Equipment MDEG License
Nature of MDEG

Patients Choice LLC 2350 W Cheyenne Ave #140, North Las Vegas, NV 89032
Name and Address of Business for Which MDEG Administrator Is Requested

Patients Choice LLC
If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Graves Jr. | Daniel | Scott
Last Name | First Name | Middle Name

"DeeJay"
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] MORNING DROP AVE. | LAS VEGAS | NV. 89129
Present Residence Address-Street or RFD | City | State/Zip

2350 W Cheyenne Ave #140 | North Las Vegas | NV 89032
Present Business Address | City | State/Zip

MANAGER/ATP | Dates 10/1/2020 - PRESENT
Present Position with the MDEG

Phone: [redacted] | Fax: (866) 725-3567

Email address: deejay@patientschoicemedical.com

[redacted] | NORWALK, HURON, OHIO
Date of Birth | Place of Birth (City, County, State)

43 | [redacted] | MALE
Age | Social Security Number | Sex

BRWN | BRWN | 190 | 6'-0"
Color of Eyes | Color of Hair | Weight | Height

Scars, tattoos or distinguishing marks and/or characteristics RIGHT SHOULDER LION TATTOO

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

If alien, registration No N/A

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

EMPLOYMENT:

A MDEG administrator must document that he or she has been employed for at least 1500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Please provide the following information to document your hours of employment.

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
OCT 2020 - PRESENT	PATIENT'S CHOICE - NV 2350 W. CHEYENNE AVE #140 NORTH LAS VEGAS, NV 89032	880 (22 WEEKS X 40)

Title	Description of Duties	Name of Supervisor
NV MGR/ATP	SPECIALIZED EQUIPMENT EVALUATIONS MGR OF PERSONNEL	PRES. JERRY MITCHELL - ATP DEL RINQUEST - CEO

Month and Year	Name/ Address of Employer/Business	No of Employed Hours
MARCH 2018 - SEPT 2020	TRUMOBILITY INC. 3100 E. CHARLESTON BLVD #104 LAS VEGAS, NV 89104	OVER 5200 (131 WEEKS) X40

Title	Description of Duties	Name of Supervisor
MGR/ATP	SPECIALIZED EQUIPMENT EVALUATIONS MGR LOCAL OPERATIONS	(801) 440+5592 DANNM LUMPKIN - CEO

*** TRUMOBILITY WAS IN UT/NV AND SOLD IN SEPT OF 2020 TO NATIONAL SEATING AND MOBILITY - ALSO IN UT/NV/OTHER STATES.

Month and Year	Name/ Address of Employer/Business	No of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/ Address of Employer/Business	No of Employed Hours

Title	Description of Duties	Name of Supervisor

I have ☐ I have not ☒ been diagnosed or treated in the last five years for a mental illness or a physical condition that would impair my ability to perform any of the essential functions of my license, including alcohol or substance abuse,

1. I have ☐ I have not ☒ been charged, arrested or convicted of a felony or misdemeanor.

2. I have ☐ I have not ☒ been the subject of an administrative action whether completed or pending.

3. I have ☐ I have not ☒ had a license suspended, revoked, surrendered or otherwise disciplined, including any action against a professional license that was not made public.

If you checked "I have" to questions 1, 2 and/or 3, please include the following information and provide a written explanation and/or documents.

a) Board Administrative Action: State: _____

b) Date: _____

Case Number: _____

c) Criminal Action: State: _____

Date: _____

Case Number: _____

County: _____

Court: _____

4. Will you be actively involved in and aware of the daily operation of the MDEG? Yes ☒ No ☐

5. Will you be employed fulltime with the MDEG? Yes ☒ No ☐

6. Will you be present at the site of the MDEG during its normal operating hours? Yes ☒ No ☐

If you answer No to questions 4, 5 or 6 please provide a written letter of explanation.

.....

.....

.....

.....

.....



Date of photograph 3/8/2021

I, Daniel Scott Graves Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a MDEG license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Revised Statutes and Regulations.

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or MDEG in the State of Nevada.

Daniel S Graves Jr.
Original Signature of Applicant 3/9/2024

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 3-9-21

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Resident MDEG License
(Nature of License)

Patients Choice LLC 2350 W Cheyenne Ave #140 North Las Vegas, NV 89032
(Name and Address of Establishment for Which License Is Requested)

Patients Choice LLC
(If applicable, Name Under Which It Is Now Operated)

1. PERSONAL INFORMATION:

Rinquest | Delbert | S
Last Name | First Name | Middle Name

N/A
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted]W Farm Springs LN, Midway, Utah 84049
Present Residence Address-Street or RFD | City | State/Zip

2350 West Cheyenne Ave. Auite #140 Dates North Las Vegas, NV 89032
Present Business Address | City | State/Zip

CEO, Founder of Patient's Choice, LLC Dates 10/16/2007-Present
Occupation

Phone: Residence [redacted]

Business 847-481-6084

[redacted]
Date of Birth | Place of Birth (City, County, State)

43 | [redacted] | Male
Age | Social Security Number or ITIN | Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Blue	Blonde	White	168	Med	6'0

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? (Yes) No If alien, registration No _____

If naturalized, certificate No _____ Date _____

Place _____ (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single Married Separated Divorced Widowed Engaged

Applicant's initial DR.

MARITAL INFORMATION-Continued

A. Current Marriage July 26, 2020 (Date) Salt Lake City, UT (City, County and State)

Spouse's full name (Maiden) Jessica Laursen SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth Salt Lake City, UT

Resident address [redacted] W Farm Springs Ln., Midway, UT 84049
(Street) (City) (State) (Zip)

Telephone: Residence [redacted] Business N/A

Spouse's employer N/A Occupation Home Maker

Address of employer N/A
(Street) (City) (State) (Zip)

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Wallace Ringuest	[redacted]	Salt Lake City	[redacted] W Farm Springs Ln, Midway UT
Will Ringquest		Woodstock, IL	W Farm Springs Ln, Midway UT
Georgia Ringquest		Woodstock, IL	W Farm Springs Ln, Midway UT

B. Child Support Information:

Please mark the appropriate response:

- ■ I am not subject to a court order for the support of child.
- ■ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ■ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial DR

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address

Contact person

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Harry H Rinquest	[redacted]	Deceased	
Mother	Elizabeth Marie Rinquest	[redacted]	West Valley, UT	Retired
Father-in-Law	Paul Laursen		[redacted] Castleview DR. WVC UT	Carpenter
Mother-in-Law				

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Renee Ringvest Taylor	[redacted]	West Jordan, UT	Nurse
Spouse	Jeremy Taylor	[redacted]	West Jordan, UT	Engineer
	David Ringvest	[redacted]	South Jordan, UT	IT Specialist
Spouse	Dezeree Ringvest (Praus)	[redacted]	South Jordan, UT	Transcriber
	Wendy Marie Young	[redacted]	Highland, UT	Marketer
Spouse	Randal S. Young	[redacted]	Highland, UT	Grounds, SLCC
	Robert Callahan Ringvest	[redacted]	Taylorsville, UT	Counselor @ Govenors University.
Spouse	Debbie (Awerkamp)	[redacted]	Taylorsville, UT	massage therapist.

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	John F Kennedy	West Valley, UT	91-94	(Yes) No
High School	Hunter High	West Valley, UT	94-97	(Yes) No
College University	Weber State University	Ogden, UT	2000-03	(Yes) No
Other				Yes No

Type of degree obtained, if any Business Management

College or university where obtained Weber State

Applicant's initial

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ~~No~~

Branch_____Date of entry-active service_____

Date of separation_____Type of discharge_____

Rating at separation_____Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ~~No~~ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ~~No~~

County_____State_____Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ~~No~~ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ~~No~~ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ~~No~~

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ~~No~~

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ~~No~~

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ~~No~~
If yes, when?_____city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ~~No~~
If yes when?_____city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ~~No~~
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial DR.

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ~~No~~ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ~~No~~ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
6/2015-9/2020	3815 360 E	Midway	UT
03/2012- 06/2015	1212 Galloway Drive	Woodstock	IL
7/2003 - 3/2012	2215 Serenity Ln	Woodstock	IL
07/2000 - 07/2003	3195 S 3600 W	WVC	UT
9/1978 - 7/2000	3642 S. Baunoch	WVC	UT

Applicant's initial RA.

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
05/2007	Patients Choice, LLC	N/A Still Own and Operate
Title	**Description of Duties**	**Name of Supervisor**
Owner	Sales, Delivery Compliance , Management	N/A

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
03 / 2003	Source One Medical Irive, CA	-to start Patients Choice
Title	**Description of Duties**	**Name of Supervisor**
Area Manager	Sales and Management	Dennis Kline (Owner)

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's Initial DR.

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Monty Tate	Home [redacted]	Double Eagle Dr.	Midway,	UT 84049	[redacted]	2
Employer Retired	Business					
Name Robert Sorenson	Home	Midway	UT	84049	[redacted]	6
Employer Sorenson Insurance	Business	(Same)				
Name Brady Spencer	Home	Herriman,	UT	84032	[redacted]	12
Employer Guardian Ins.	Business					
Name Julian Crithfield	Home	Highland,	UT	80536	[redacted]	8
Employer IT Drones	Business					
Name Brandon Cope	Home	Midway,	UT	84049	[redacted]	5
Employer Cope Investments	Business					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes (No)
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes (No)
If yes, state type, where and years held

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes (No) 3-9-21 MR.
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Patients Choice operates in several other states as we have in Nevada. Those include *IL (corp. office), *GA, *IN, MO, *TX, *CO, UT w/ Brick + mortar in states with * I also own a retail ~~division in~~ Business in IL called Choice Mobility DBA. I also own Scooter Chair Repair, DBA Patients Choice, our division in Georgia.

Applicant's initial MR.

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes (No)

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes (No)

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes (No)

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes (No)

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes (No)

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes (No)

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes (No)



Date of photograph 3-9-21

Applicant's initial DA

STATE OF Nevada

ss.

COUNTY OF Clark

I, Delbert Rinquest, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 9th day of March 2021

Notary Public

Comission Exp. 5/18/2024

(seal)

Mercedes Gant
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 20-0951-01
My Appt. Expires May 18, 2024

Applicant's initial DR.

ADDITIONAL INFORMATION

I own 100% of Patients Choice and am actively involved in operations. We do business in several states and have 5 physical locations similar to this new location we now have in North Las Vegas. Thank You!

Applicant's initial DJR.

File Number 0219900-9

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that

PATIENT'S CHOICE, LLC, HAVING ORGANIZED IN THE STATE OF ILLINOIS ON MAY 14, 2007, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE LIMITED LIABILITY COMPANY ACT OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LIMITED LIABILITY COMPANY IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 17TH *day of* NOVEMBER ***A.D.*** 2020 .

Authentication #: 2032200558 verifiable until 11/17/2021
Authenticate at: http://www.cyberdriveillinois.com

Jesse White

SECRETARY OF STATE

Executive Committee

Del Rinquest
CEO - Owner
3601 Edison Place
(847) 772-2941
Chief Executive Officer

Brigit Bourget
Reimbursement Manager, Liaison Team Lead
3601 Edison Place
(847) 380-1292
Reimbursement Manager, Liaison Manager

Jerry Mitchell
President, ATP, CRTS, Rehab Consultant
3601 Edison Place
(630) 639-2317
President, ATP, CRTS

Todd Davis
HR, Business Manager
3601 Edison Place
(847) 242-8854
Business Manager

Maryam Ali
Compliance Manager
3601 Edison Place
(224) 347-4787
Compliance Manager

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 10/19/2020

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

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

PRODUCER
The Buckner Company
6550 S Millrock, Suite #300
Salt Lake City UT 84121

License#: 92480

CONTACT NAME: Jennifer Eckersley
PHONE (A/C, No, Ext): 801-937-6719 FAX (A/C, No):
E-MAIL ADDRESS: jeckersley@buckner.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Continental Casualty Company	20443
INSURER B : The Continental Insurance Company	35289
INSURER C : American Casualty Company of Reading, PA	20427
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patient's Choice, LLC
2350 W. Cheyenne Ave #140
North Las Vegas NV 89032

PATICHO-01

COVERAGES **CERTIFICATE NUMBER:** 68072445 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			2097767256	5/11/2020	5/11/2021	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			4024485712	5/11/2020	5/11/2021	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	DED [ ] RETENTION $							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			WC429430220	5/11/2020	5/11/2021	X PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

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

CERTIFICATE HOLDER

Alexander and Belmont, LLC
6130 Washburn St
Las Vegas, NV 89032

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 9/23/2020

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

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

PRODUCER
The Buckner Company
6550 S Millrock, Suite #300
Salt Lake City UT 84121

License#: 92480

CONTACT NAME: Jennifer Eckersley
PHONE (A/C, No, Ext): 801-937-6719 **FAX (A/C, No):**
E-MAIL ADDRESS: jeckersley@buckner.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Continental Casualty Company	20443
INSURER B : The Continental Insurance Company	35289
INSURER C : American Casualty Company of Reading, PA	20427
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Patient's Choice LLC
3601 Edison Place
Rolling Meadows IL 60008
PATICHO-01

COVERAGES **CERTIFICATE NUMBER:** 2018896903 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			2097767256	5/11/2020	5/11/2021	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 4,000,000
	OTHER:							$
B	AUTOMOBILE LIABILITY			4024485712	5/11/2020	5/11/2021	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC429430220	5/11/2020	5/11/2021	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$ 500,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 500,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Location: 3601 Edison Place Rolling Meadows, IL 60008
Otto Landholdings LLC is Additional Insured for General Liability per form SB146932E (6-11).

CERTIFICATE HOLDER

Otto Landholdings LLC
3603 Edison Place
Rolling Meadows IL 60008

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

CNA

SB-146932-E
(Ed. 06/11)

THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

BLANKET ADDITIONAL INSURED – LIABILITY EXTENSION

This endorsement modifies insurance provided under the following:

BUSINESSOWNERS LIABILITY COVERAGE FORM

Coverage afforded under this extension of coverage endorsement does not apply to any person or organization covered as an additional insured on any other endorsement now or hereafter attached to this Policy.

1. ADDITIONAL INSURED – BLANKET VENDORS

WHO IS AN INSURED is amended to include as an additional insured any person or organization (referred to below as vendor) with whom you agreed, because of a written contract or agreement to provide insurance, but only with respect to "bodily injury" or "property damage" arising out of "your products" which are distributed or sold in the regular course of the vendor's business, subject to the following additional exclusions:

1. The insurance afforded the vendor does not apply to:

   a. "Bodily injury" or "property damage" for which the vendor is obligated to pay damages by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability for damages that the vendor would have in the absence of the contract or agreement;

   b. Any express warranty unauthorized by you;

   c. Any physical or chemical change in the product made intentionally by the vendor;

   d. Repackaging, except when unpacked solely for the purpose of inspection, demonstration, testing, or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;

   e. Any failure to make such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products;

   f. Demonstration, installation, servicing or repair operations, except such operations performed at the vendor's premises in connection with the sale of the product;

   g. Products which, after distribution or sale by you, have been labeled or relabeled or used as a container, part or ingredient of any other thing or substance by or for the vendor; or

   h. "Bodily injury" or "property damage" arising out of the sole negligence of the vendor for its own acts or omission or those of its employees or anyone else acting on its behalf. However, this exclusion does not apply to:

      (1) The exceptions contained in Subparagraphs **d.** or **f.**; or

      (2) Such inspections, adjustments, tests or servicing as the vendor has agreed to make or normally undertakes to make in the usual course of business, in connection with the distribution or sale of the products.

2. This insurance does not apply to any insured person or organization, from whom you have acquired such products, or any ingredient, part or container, entering into, accompanying or containing such products.

3. This provision **2.** does not apply to any vendor included as an insured by an endorsement issued by us and made a part of this Policy.

4. This provision **2.** does not apply if "bodily injury" or "property damage" included within the "products-completed operations hazard" is excluded either by the provisions of the Policy or by endorsement.

2. MISCELLANEOUS ADDITIONAL INSUREDS

WHO IS AN INSURED is amended to include as an insured any person or organization (called additional insured) described in paragraphs **2.a.** through **2.h.** below whom you are required to add as an additional insured on this policy under a written contract or agreement but the written contract or agreement must be:

1. Currently in effect or becoming effective during the term of this policy; and

2. Executed prior to the "bodily injury," "property damage" or "personal and advertising injury," but

Only the following persons or organizations are additional insureds under this endorsement and coverage provided to such additional insureds is limited as provided herein:

a. Additional Insured – Your Work

That person or organization for whom you do work is an additional insured solely for liability

4002000562097767252618

due to your negligence specifically resulting from your work for the additional insured which is the subject of the written contract or written agreement. No coverage applies to liability resulting from the sole negligence of the additional insured.

The insurance provided to the additional insured is limited as follows:

(1) The Limits of Insurance applicable to the additional insured are those specified in the written contract or written agreement or in the Declarations of this policy, whichever is less. These Limits of Insurance are inclusive of, and not in addition to, the Limits of Insurance shown in the Declarations.

(2) The coverage provided to the additional insured by this endorsement and paragraph **F.9.** of the definition of "insured contract" under **Liability and Medical Expenses Definitions** do not apply to "bodily injury" or "property damage" arising out of the "products-completed operations hazard" unless required by the written contract or written agreement.

(3) The insurance provided to the additional insured does not apply to "bodily injury," "property damage," or "personal and advertising injury" arising out of the rendering or failure to render any professional services.

b. State or Political Subdivisions

A state or political subdivision subject to the following provisions:

(1) This insurance applies only with respect to the following hazards for which the state or political subdivision has issued a permit in connection with premises you own, rent, or control and to which this insurance applies:

(a) The existence, maintenance, repair, construction, erection, or removal of advertising signs, awnings, canopies, cellar entrances, coal holes, driveways, manholes, marquees, hoistaway openings, sidewalk vaults, street banners, or decorations and similar exposures; or

(b) The construction, erection, or removal of elevators; or

(2) This insurance applies only with respect to operations performed by you or on your behalf for which the state or political subdivision has issued a permit.

This insurance does not apply to "bodily injury," "property damage" or "personal and advertising injury" arising out of operations performed for the state or municipality.

c. Controlling Interest

Any persons or organizations with a controlling interest in you but only with respect to their liability arising out of:

(1) Their financial control of you; or

(2) Premises they own, maintain or control while you lease or occupy these premises.

This insurance does not apply to structural alterations, new construction and demolition operations performed by or for such additional insured.

d. Managers or Lessors of Premises

A manager or lessor of premises but only with respect to liability arising out of the ownership, maintenance or use of that specific part of the premises leased to you and subject to the following additional exclusions:

This insurance does not apply to:

(1) Any "occurrence" which takes place after you cease to be a tenant in that premises; or

(2) Structural alterations, new construction or demolition operations performed by or on behalf of such additional insured.

e. Mortgagee, Assignee or Receiver

A mortgagee, assignee or receiver but only with respect to their liability as mortgagee, assignee, or receiver and arising out of the ownership, maintenance, or use of a premises by you.

This insurance does not apply to structural alterations, new construction or demolition operations performed by or for such additional insured.

f. Owners/Other Interests – Land is Leased

An owner or other interest from whom land has been leased by you but only with respect to liability arising out of the ownership, maintenance or use of that specific part of the land leased to you and subject to the following additional exclusions:

This insurance does not apply to:

(1) Any "occurrence" which takes place after you cease to lease that land; or

CNA

(2) Structural alterations, new construction or demolition operations performed by or on behalf of such additional insured.

g. **Co-owner of Insured Premises**

A co-owner of a premises co-owned by you and covered under this insurance but only with respect to the co-owners liability as co-owner of such premises.

h. **Lessor of Equipment**

Any person or organization from whom you lease equipment. Such person or organization are insureds only with respect to their liability arising out of the maintenance, operation or use by you of equipment leased to you by such person or organization. A person's or organization's status as an insured under this endorsement ends when their written contract or agreement with you for such leased equipment ends.

With respect to the insurance afforded these additional insureds, the following additional exclusions apply:

This insurance does not apply:

(1) To any "occurrence" which takes place after the equipment lease expires; or

(2) To "bodily injury," "property damage" or "personal and advertising injury" arising out of the sole negligence of such additional insured.

Any insurance provided to an additional insured designated under paragraphs **b.** through **h.** above does not apply to "bodily injury" or "property damage" included within the "products-completed operations hazard."

3. The following is added to **Paragraph H.** of the **BUSINESSOWNERS COMMON POLICY CONDITIONS:**

H. Other Insurance

4. This insurance is excess over any other insurance naming the additional insured as an insured whether primary, excess, contingent or on any other basis unless a written contract or written agreement specifically requires that this insurance be either primary or primary and noncontributing.

4. **LEGAL LIABILITY – DAMAGE TO PREMISES**

A. Under B. Exclusions, 1. Applicable to Business Liability Coverage, Exclusion **k. Damage To Property,** is replaced by the following:

k. Damage To Property

"Property damage" to:

1. Property you own, rent or occupy, including any costs or expenses incurred by you, or any other person, organization or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;

2. Premises you sell, give away or abandon, if the "property damage" arises out of any part of those premises;

3. Property loaned to you;

4. Personal property in the care, custody or control of the insured;

5. That particular part of any real property on which you or any contractors or subcontractors working directly or indirectly in your behalf are performing operations, if the "property damage" arises out of those operations; or

6. That particular part of any property that must be restored, repaired or replaced because "your work" was incorrectly performed on it.

Paragraph 2 of this exclusion does not apply if the premises are "your work" and were never occupied, rented or held for rental by you.

Paragraphs 1, 3, and 4, of this exclusion do not apply to "property damage" (other than damage by fire or explosion) to premises:

(1) rented to you:

(2) temporarily occupied by you with the permission of the owner, or

(3) to the contents of premises rented to you for a period of 7 or fewer consecutive days.

A separate limit of insurance applies to Damage To Premises Rented To You as described in Section D – Liability and Medical Expenses Limits of Insurance.

4002005520977572562619

Paragraphs 3, 4, 5, and 6 of this exclusion do not apply to liability assumed under a sidetrack agreement.

Paragraph 6 of this exclusion does not apply to "property damage" included in the "products-completed operations hazard."

B. Under **B. Exclusions, 1. Applicable to Business Liability Coverage,** the last paragraph of 2. Exclusions is deleted and replaced by the following:

Exclusions **c, d, e, f, g, h, i, k, l, m, n, and o,** do not apply to damage by fire to premises while rented to you or temporarily occupied by you with permission of the owner or to the contents of premises rented to you for a period of 7 or fewer consecutive days. A separate limit of insurance applies to this coverage as described in **Section D. Liability And Medical Expenses Limits Of Insurance.**

C. The first Paragraph under item **5. Damage To Premises Rented To You Limit of Section D. Liability And Medical Expenses Limits Of Insurance** is replaced by the following:

The most we will pay under Business Liability for damages because of **"property damage" to any one premises,** while rented to you, or temporarily occupied by you, with the permission of the owner, including contents of such premises rented to you for a period of 7 or fewer consecutive days, is the Damage to Premises Rented to You limit shown in the Declaration.

5. **Blanket Waiver of Subrogation**

We waive any right of recovery we may have against:

a. Any person or organization with whom you have a written contract that requires such a waiver.

6. **Broad Knowledge of Occurrence**

The following items are added to **E. Businessowners General Liability Conditions** in the **Businessowners Liability Coverage Form:**

e. Paragraphs **a.** and **b.** apply to you or to any additional insured only when such "occurrence," offense, claim or "suit" is known to:

(1) You or any additional insured that is an individual;

(2) Any partner, if you or an additional insured is a partnership;

(3) Any manager, if you or an additional insured is a limited liability company;

(4) Any "executive officer" or insurance manager, if you or an additional insured is a corporation;

(5) Any trustee, if you or an additional insured is a trust; or

(6) Any elected or appointed official, if you or an additional insured is a political subdivision or public entity.

This paragraph **e.** applies separately to you and any additional insured.

7. **Bodily Injury**

Section **F. Liability and Medical Expenses Definitions,** item 3. "Bodily Injury" is deleted and replaced with the following:

"Bodily injury" means bodily injury, sickness or disease sustained by a person, including death, humiliation, shock, mental anguish or mental injury by that person at any time which results as a consequence of the bodily injury, sickness or disease.

8. **Expanded Personal and Advertising Injury Definition**

a. The following is added to **Section F. Liability and Medical Expenses Definitions, item 14. Personal and Advertising Injury, in the Businessowners General Liability Coverage Form:**

h. Discrimination or humiliation that results in injury to the feelings or reputation of a natural person, but only if such discrimination or humiliation is:

1. Not done intentionally by or at the direction of:

a. The insured; or

b. Any "executive officer," director, stockholder, partner, member or manager (if you are a limited liability company) of the insured; and

2. Not directly or indirectly related to the employment, prospective employment, past employment or termination of employment of any person or person by any insured.

b. The following is added to Exclusions, **Section B.:**

CNA

(15) Discrimination Relating to Room, Dwelling or Premises

Caused by discrimination directly or indirectly related to the sale, rental, lease or sub-lease or prospective sale, rental, lease or sub-lease of any room, dwelling or premises by or at the direction of any insured.

(16) Fines or Penalties

Fines or penalties levied or imposed by a governmental entity because of discrimination.

c. This provision **(Expanded Personal and Advertising Injury)** does not apply if **Personal and Advertising Injury Liability** is excluded either by the provisions of the Policy or by endorsement.

9. Personal and Advertising Injury Re-defined

Section F. Liability and Medical Expenses Definitions, item 14, Personal Advertising Injury, Paragraph c. is replaced by the following:

c. The wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room dwelling or premises that a person or organization occupies committed by or on behalf of it's owner, landlord or lessor.

4002005620977672562620

View/Print Label

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialogue box that appears. Note: If your browser does not support this function, select Print from the File menu to print the label.

2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**

   Customers with a scheduled Pickup
   - Your driver will pickup your shipment(s) as usual.

   Customers without a scheduled Pickup
   - Schedule a Pickup on ups.com to have a UPS driver pickup all of your packages.
   - Take your package to any location of The UPS Store®, UPS Access Point(TM) location, UPS Drop Box, UPS Customer Center, Staples® or Authorized Shipping Outlet near you. To find the location nearest you, please visit the 'Locations' Quick link at ups.com.

UPS Access Point™
TOTAL WIRELESS 97
97 MAMARONECK AVE
WHITE PLAINS NY 10601-5204

UPS Access Point™
WESTCHESTER ROAD RUNNER
179 E POST RD
WHITE PLAINS NY 10601-4901

UPS Access Point™
ADVANCE AUTO PARTS STORE 4514
22 WESTMORELAND AVE
WHITE PLAINS NY 10606-1913

FOLD HERE



CT

March 11, 2021

UI Tax / Employer Accounts.
220 French Landing Dr., 3-B,
Nashville, TN 37243

Re: **State and Liberty Clothing Company LLC**
Unemployment Tax Registration

To Whom It May Concern:

Enclosed please find an **Unemployment Tax Registration** for our client **State and Liberty Clothing Company LLC.** Once the application has been processed, please forward evidence of approval to the mailing address on the application. If there is any issue, or if you require any further information, please do not hesitate to contact us.

Thank you,

LicenseLogix
140 Grand Street, Suite 300
White Plains, NY 10601
service@licenselogix.com

RETURN TO: TN DEPT OF LABOR AND WORKFORCE DEVELOPMENT
EMPLOYER ACCOUNTS/EMPLOYER SERVICES 220
FRENCH LANDING DRIVE, 3-B
NASHVILLE TN 37243-1002
PHONE (615) 741-2486 FAX (615) 741-7214
EMAIL: EMPLOYERSTATUS.RATES@TN.GOV

TENNESSEE DEPARTMENT OF LABOR AND WORKFORCE DEVELOPMENT

REPORT TO DETERMINE STATUS
APPLICATION FOR EMPLOYER NUMBER

1. Enter Federal Number, Business Name and Address

Federal Number 47-2540542 ☐

Employer Name State and Liberty Clothing Co

Trade Name N/A

Mailing Address 670 Airport Blvd., STE. 1
Ann Arbor, Michigan, 48108

Physical Business Address in Tennessee (other than employee residence) if different from above:
5053 Broadway Pl, Nashville TN 37203

Business Website: stateandliberty.com

Phone: 301-502-5362 Fax: N/A

Email Address: steven@stateandliberty.com

OFFICIAL USE ONLY

Tennessee ID Number	M. No.	County	Alt Zip

Liab. Org.	First Employment	Date Liable

Comp Year	NAICS	M-NAICS	Verified

Previous No.	Rate

2. Have you previously had an account with this department? ☐ YES ☒ NO **If YES, Account Number** N/A

3. Is your organization a Professional Employer Organization (PEO)? ☐ YES ☒ NO If YES, **Tennessee** license number N/A
Is your organization a client of a Professional Employer Organization (PEO)? ☐ YES ☒ NO
If YES, STOP. STOP **Please complete LB-0910, Application for Client Number.**
NOTE: If corporation is a nonprofit, exempt from Federal Income Taxes under Section 501(C)(3) of the IRS Code, STOP. STOP
Please complete LB-0444, Report to Determine Status, Nonprofit Organization.

4. CHECK (X) FORM OF ORGANIZATION

- ☐ INDIVIDUAL
- ☐ PARTNERSHIP
- ☐ CORPORATION
- ☒ LIMITED LIABILITY COMPANY
- ☐ LIMITED PARTNERSHIP
- ☐ OTHER

5. Name of Owner, Partners, Corporate Officers, Limited Liability Company Members and Managers *(If Board Managed)*, General Partners *(Attach separate sheet if necessary.)*

Name	Social Security Number
Steven Fisher, CEO	[redacted]
Lee Moffie, President	

NOTE: If a Limited Liability Company, are you treated by IRS as a(n) ☐ **Individual Proprietorship** ☐ **Partnership or as a** ☒ **Corporation?**

6. Name of person responsible for payroll records Steven Fisher Phone Number 301-502-5362

7. A. Number of workers you have employed (will employ) in TN 2

B. Date you first employed (will employ) a worker in TN 3/1/2021

C. Date you first paid (will pay) a worker in Tennessee 3/1/2021

D. Are you presently reporting for U.I. purposes in another state? ☒ YES ☐ NO If YES, which state? Michigan

E. If a corporation or LLC, provide formation information.
Date 3/1/2021 State MI Control No. 801764118

8. REGULAR BUSINESS EMPLOYMENT (SEPARATE REPORTS MUST BE FILED FOR EACH CALENDAR QUARTER IN WHICH WAGES WERE PAID.)

A. Have you employed or do you expect to employ at least one worker in twenty different calendar weeks during a calendar year? ☒ YES ☐ NO
If YES, give earliest month and year the twentieth week occurred (will occur). MONTH March YEAR 2021

B. Have you had or do you expect to have a quarterly payroll of $1,500 or more? ☒ YES ☐ NO
If YES, give earliest quarter and year this occurred (will occur). QUARTER 1 YEAR 2021

9. HOUSEHOLD EMPLOYMENT (SEPARATE REPORTS MUST BE FILED FOR EACH CALENDAR QUARTER IN WHICH WAGES WERE PAID.)

A. Have you had or do you expect to have a $1,000 quarterly payroll for domestic services? ☐ YES ☐ NO
If YES, give earliest quarter and year this occurred (will occur). QUARTER N/A YEAR N/A

10. AGRICULTURAL EMPLOYMENT (SEPARATE REPORTS MUST BE FILED FOR EACH CALENDAR QUARTER IN WHICH WAGES WERE PAID.)

A. Have you employed or do you expect to employ at least ten or more workers in some part of a day in twenty different weeks during a calendar year? ☐ YES ☐ NO If YES, give earliest month and year this occurred (will occur). MONTH N/A YEAR N/A

B. Have you had or do you expect to have a quarterly payroll of $20,000 or more? ☐ YES ☐ NO
If YES, give earliest quarter and year this occurred (will occur). QUARTER N/A YEAR N/A

C. Is all activity performed on a farm? ☐ YES ☐ NO If NO, what percentage is? N/A Please explain in 13A on page 2.

Must be signed by owner, partner, authorized limited liability company member or manager, or officer of the corporation.

Signature [signature] Title Steven Fisher, CEO Date 03-10-21

PLEASE COMPLETE PAGE 2.
FAILURE TO DO SO WILL RESULT IN RECEIVING THE HIGHEST PREMIUM RATE ASSIGNABLE

11. (A) Name and Address of predecessor employer N/A

(B) Account Number of predecessor employer N/A **(C)** Date of acquisition N/A

(D) Did you acquire all of your predecessor's business in Tennessee? ☐ YES ☐ NO If No, what percentage did you acquire? _____

(E) Did your predecessor continue in business in Tennessee? ☐ YES ☐ NO

(F) Tennessee Employment Security Law provides for the mandatory transfer of an employer's benefit and premium experience whenever there is any common ownership, management or control between the predecessor and successor employers.
Did any owner or manager of this company have an ownership interest in or participate in the management or control of the business acquired? ☐ YES ☐ NO
If "YES," please explain: _____
Per TCA 50-7-403(b)(2)(C)(ii) "Common ownership, management or control" includes any individual who has at least a 10%ownership interest in - or who participates in the management or control of - the predecessor's trade or business and has a relative with a 10% ownership interest in - or who participates in the management or control of - the successor's trade or business.
Does anyone who had a 10% or more ownership interest in the previous company - or who participated in its management or control - have a relative with a 10% or more interest in this company or who participates in its management or control?
☐ YES ☐ NO If "YES," please explain: _____
If you are not subject to a mandatory transfer of experience but wish to succeed to the experience of the predecessor employer, Form LB-0483, Application for Transfer of Experience Rating Record, must be submitted by no later than the end of the quarter following the quarter in which the acquisition occurred.

12. Enter below the amount of total payroll for each quarter in which you have had or expect to have employment.

YEAR	JAN-MAR	APR-JUNE	JUL-SEPT	OCT-DEC	YEAR	JAN-MAR	APR-JUNE	JUL-SEPT	OCT-DEC
2021	$10000	$30000	$30000	$30000					

13. FAILURE TO PROPERLY COMPLETE THIS SECTION WILL RESULT IN RECEIVING THE HIGHEST PREMIUM RATE ASSIGNABLE.

(A) Describe the major business activity of the account to be covered, listing any products manufactured or sold, or service provided. **Be as descriptive as possible.** Selling men's clothing

(B) In what **Tennessee County** is your company located? Davidson County
(If account covers sales reps or other personnel working from home, list county or city of residence.) N/A

(C) Is the primary purpose of the employee(s) covered by this application to **support other locations of your company?** ☐ YES ☒ NO
If YES, then check the category that best applies. Add comments as necessary. N/A

- ☐ HEADQUARTERS (e.g., corporate or regional management offices) N/A
- ☐ ADMINISTRATIVE (e.g., bookkeeping, accounting, payroll, HR, PR) N/A
- ☐ WAREHOUSING (e.g., storage, distribution, equipment yard) N/A
- ☐ SALESMAN (indicate product) N/A
- ☐ INFORMATION TECHNOLOGY (e.g., software publication, programming, systems design, data processing)
- ☐ OTHER (e.g., repair shop, security office, maintenance, employee recreation facility)

(D) Below are some industries that often need additional clarification. This section may not apply to every employer. If you see your industry, please answer the corresponding question(s):

Construction: What type of construction? _____ ***Mostly*** ☐ residential or ☐ non-residential?

Property Mgmt.: Does this business manage property for ☐ others or for ☐ itself? ***Mostly*** ☐ residential or ☐ non-residential?

Trucking: Is the main trucking activity ☐ local or ☐ long distance? ***Mostly*** ☐ truckload or ☐ less than truckload?

Empl. Agency: Is this a ☐ Temporary Staffing Service or an ☐ Employment Placement Agency?

Health Care: Is this a ☐ Doctor's Office, ☐ Multi-Disciplinary Clinic, ☐ Freestanding Urgent Care Center or ☐ Other?
Please specify: _____

Info Tech (IT): Which category best fits your business? ☐ Software Publication, ☐ Programming, ☐ Systems Design, ☐ Data Processing Is

Restaurant: the restaurant ☐ Full Service, ☐ Fast Food, ☐ Cafeteria/Buffet, ☐ Snack Bar, ☐ Other? Please specify: _____

Consulting: What is the primary type of consulting? ☐ Administrative, ☐ Human Resources, ☐ Marketing, ☐ Process/Logistics,
☐ Environmental, or ☐ Other - Please specify: _____

Home Health: Does the care involve skilled nursing? ☐ YES ☐ NO

Retail: What is the primary product? Selling men's clothing

Wholesale: What is the primary product? _____

Mining: What is the primary product? _____

Convenience Store: Does the store sell gasoline? ☐ YES ☐ NO

Manufacturing: What is the primary product? _____

INFORMATION FOR COMPLETING STATUS APPLICATION

Enclosed is a Report to Determine Status/Application for Employer Number. The Tennessee Employment Security Law and Regulations requires each employing unit in Tennessee to file this report with the Department of Labor and Workforce Development for the purpose of determining status. If you answer "Yes" to question 7(d) or any one of the questions in items 8, 9 or 10 on the status application, you are liable for unemployment insurance coverage with this department. Please complete and submit the enclosed form as soon as you have paid wages for services performed in Tennessee.

The requirements for liability are:

REGULAR BUSINESS EMPLOYERS

Items 8 A and B on the status application do not pertain to farm or household employees.

Item 8A. During some part of a day in each of twenty calendar weeks of a calendar year, did you employ or do you expect to employ one or more persons? (The weeks need not be consecutive and both full and part-time workers are counted.)

OR

Item 8B. Have you paid or do you expect to pay wages of **$1,500** or more in any calendar quarter?

HOUSEHOLD EMPLOYERS

Item 9A. Did you have or do you expect to have a calendar quarter in which you paid household employee(s) **$1,000** or more in cash wages? If so, you are liable for all wages paid during that year and the following calendar year.

AGRICULTURAL EMPLOYERS

Item 10A. During some part of a day in each of twenty weeks of a calendar year did you employ or do you expect to employ ten or more persons? (The weeks need not be consecutive and both full and part-time workers are counted.)

OR

Item 10B. Have you paid or do you expect to pay wages of **$20,000** or more in any calendar quarter?

Leave the space under Item 1 for Federal Number blank if you have not yet been assigned a FEIN (Federal Employer Identification Number). You will receive a letter asking for this number after we establish your state account. Return the letter with your FEIN when you receive the number from the Internal Revenue Service.

If you are completing quarterly reports and/or the Application for Transfer of Experience Rating (LB-0483), please return them in the same envelope with this application. **DO NOT** write in the box titled **State Account Number** if you are submitting quarterly Premium (LB-0456) and Wage (LB-0851) Reports along with this application. Your new number will be recorded here when assigned.

Anyone who is paid for personal services by a corporation is considered to be an employee of the corporation **even if** that person is an officer and/or owns stock in the corporation.

NOTE: PLEASE BE SURE TO **SIGN** YOUR STATUS APPLICATION at the bottom and include the appropriate information. Also, complete both pages of your Status Application form.

Failure to complete both pages of the application or to provide sufficient information upon which to correctly classify the industry code will result in the highest new employer rate being assigned.

Mail To: TN Dept of Labor and Workforce Development
Division of Employment Security
Employer Accounts/Employer Services
220 French Landing Drive, 3-B
Nashville TN 37243-1002

PREMIUM RATE INFORMATION

New employers in Tennessee are initially subject to a "new employer" rate until their account has been subject to premiums and chargeable with benefits for thirty-six consecutive months ending on the computation date (December 31 of each year). They then become eligible, beginning on the next July 1, for a premium rate based on their individual reserve experience.

New employer rates are determined separately for each major industry group based on the combined reserve experience of each industry group as a whole. Presently, all industries, except construction, have a new employer rate of 2.7%. The new employer rates for construction, mining, and manufacturing are listed below.

Rate Year	Construction	Mining and Extraction	Manufacturing		
			Sector 31 ●	Sector 32 ■	Sector 33 ◆
July '14 – June '15	7.0%	5.0%	2.7%	2.7%	5.5%
July '15 – June '16	6.5%	2.7%	2.7%	2.7%	5.0%
July '16 – June '17	6.0%	2.7%	2.7%	2.7%	2.7%
July '17 – June '18	6.0%	2.7%	2.7%	2.7%	2.7%
July '18 – June '19	5.5%	2.7%	2.7%	2.7%	2.7%
July '19 – June '20	5.0%	2.7%	2.7%	2.7%	2.7%
July '20 – June '21	5.0%	2.7%	2.7%	2.7%	2.7%

- ● NAICS Manufacturing Sector 31 includes food, beverage, and tobacco products, as well as textiles, leather, and apparel products.
- ■ NAICS Manufacturing Sector 32 includes wood products, paper products, printing and related support activities, petroleum and coal products, chemical manufacturing, plastics and rubber products, and nonmetallic mineral products.
- ◆ NAICS Manufacturing Sector 33 includes metal products, machinery, computer and electronic products, electrical equipment, appliances, transportation equipment, and furniture manufacturing.

14

14A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR NEVADA WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ **New Wholesaler** ☐ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: WH_____)

☐ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☒ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: Biologic LLC.

Physical Address: 8420 S. Eastern Ave. Ste 101 LasVegas, Nv 89123

Mailing Address: 593 Caribbean Palm Dr. LasVegas Nv 89138

City: Las Vegas State: NV Zip Code: 89138

Telephone: 702 385 6488 Fax: _____

Toll Free Number: _____

E-mail: stallingsv@gmail.com Website: _____

Facility Manager: Vanessa Stallings

Professional qualifications and experience of facility manager: Previous wholesaler experience.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled be firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: BIOLOGICS, LLC
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR NEVADA WHOLESALER LICENSE

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate.)

Licensed as a Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of the FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1) N/A
Name Address
Business

2)
Name Address
Business

3)
Name Address
Business

4)
Name Address
Business

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

per Guru chavan 3/25/21

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

APPLICATION FOR NEVADA WHOLESALER LICENSE

This page must be submitted for all types of ownership.

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

V. Stallings

Original Signature of Person Authorized to Submit Application, no copies or stamps

Vanessa Stallings

Print Name of Authorized Person

10/23/2020

Date

Board Use Only	Received:_____	Amount: 500.00

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: Nevada

Parent Company if any: N/A

Corporation Name: BIOLOGIC LLC.

Mailing Address: 593 Caribbean Palm Drive

City: Las Vegas State: NV Zip: ~~89038~~ (89138)

Telephone: 702 385 6488 Fax:

Contact Person: Michael Ping

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a) Guru Charan 593 Caribbean Palm Dr. Las Vegas, NV 89138
Name Address

b) Michael Ping 8420 S. Eastern Ave Ste 101 Las Vegas, NV 89123
Name Address

c) _____
Name Address

d) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses.*

2) Provide the number of shares issued by the corporation. 100

3) What was the price paid per share? $1.00

4) What date did the corporation actually receive the cash assets? 9/2020

5) **Provide a copy of the corporation's stock register evidencing the above** information

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A PARTNERSHIP.

List names of 4 largest partners and percentage of ownership:

Name: Guru Charan %: 50

Name: Michael Ping %: 50

Name: %:

Name: %:

Partnership Name: Biologic, LLC

Mailing Address: 6980 O' Bannon Dr. Las Vegas, Nv 89117

City: Las Vegas State: Nevada Zip: 89117

Telephone: 650 714 6577 Fax:

Contact Person: Michael Ping

Include with the application for a partnership

Complete personal history record for each stockholder. Download the form from the website **under the "New Applications" tab. The forms are available under the** *documents for all types of businesses*. Must be original signature(s), no copies or stamp.

Designated representative form. Download the form from the **website under the "New Applications" tab. The forms are available under the** *documents for all types of businesses*.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an examination on law **prior** to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee.

***If VAWD certified by NABP, fingerprints and list of employees are not required. You will need to complete the following:

- Please provide a copy of your VAWD certification.
- Copy of a bond in an amount of $25,000.00 made payable to the State of Nevada. A bond or other form of security must be current in order to maintain and keep a Nevada wholesaler registration. **Download the form from the website under the "New Applications" tab. The** forms are available under the documents for wholesalers only.

Mark I. Sedar

From: Mike Ping [redacted]
Sent: Wednesday, March 10, 2021 1:09 PM
To: Mark I. Sedar
Cc: Vanessa Stallings
Subject: Nevada BOP application for BioLogic wholesalers license

Hi Mark,

It was a pleasure speaking with you today.

One of the two items which you requested additional information stems from a business dispute in 2009; which was 8 years after our California specialty pharmacy was acquired. I was fully engaged in other investments including private money lending for real estate projects, and developing expensive homes throughout the San Francisco Bay Area. A landscaper we hired to perform significant work on one home continued to ask for money before his work was completed. He asked me for a post-dated check so he could show that to a friend and borrow the money he needed to finish our job. Needless to say he finished the job with inferior materials and landscaping that fell below the specifications required in the contractors agreement. A civil case followed, but he misrepresented the facts and accused me of writing a bad check (even though I placed a stop payment on the check). After we settled all legal actions were dismissed with prejudice as recorded at the San Mateo County Superior Courts records.

The last item you raised occured about 2015 in Arizona. I am 59 old and never had any domestic abuse or assault issues with our society. After relocating to Chandler, Arizona around 2013 to be close to my children and not knowing anyone else other than my ex-wife. I met and started dating a lady who turned out to be unbalanced. I moved her into my home after she told me she was diagnosed with cancer and had no one to care for her. I had planned to provide her the care she would require during the treatment. However, she continued to drink excessively while self-medicating (xanax, clonazepam.. as I learned later including past DUIs, etc). When I discovered she was untruthful about her cancer and basically an unhealthy individual I ended the relationship and moved her out of my home. Days later she wrongfully accused me of assault. After a trial and the facts came out, all felony claims were dismissed and a single count misdemeanor for disturbing the peace or something was determined. We appealed the verdict and lost.

I hope this additional information answers any questions as to these two items, or furthermore my character as a professional and person. Please let me know if there is anything else required to progress with the wholesalers permit we seek.

--
Michael Ping
Executive Director
M: [redacted]

Valley Oaks Medical Group

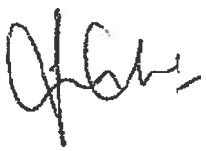
Guru Charan Legal Disclosure

On December 30th 2004, my ex-wife filed a complaint against me alleging abusive behavior with the Sacramento, California police where we resided at that time. The police arrested me based on the complaint the same day. Upon further investigation, it was determined that the accusations were false and I was immediately released from custody.

No charges were filed against me as a result of this incident. Please refer to the attached "Local Criminal Record Search Response Form" issued by the Superior Court of California and the police report from Folsom Police Department that attests to this fact.

Eventually, we filed a divorce petition with the California courts to end the marriage. This divorce was granted on June 21st 2005.

Thanks,



Guru Charan 02/25/2021

Sacramento County District Attorney's Office

Summary for Referral # FPD-04-00006737

Status: REJECTED

Team: DOMESTIC VIOLENCE PROGRAM

DA: MOLLY STEBER

Printed: August 08, 2007

Case Flags:

Defendant Information

Defendant: CHARAN, GURU

XREF # 3990992

DOB: [redacted]

Sex: M SSN: [redacted]

DL # [redacted]

DL State:

CDC #

FBI #

State ID # [redacted]

Docket #

Arrest # 0892257901

Arrest Date: 12/30/2004

Defendant Flags

DOMESTIC VIOLENCE

Events

Event: 01/03/2005 DEFENDANT RECEIVED

Dispo: 01/03/2005 Computer Generated

Event: 01/03/2005 INTAKE-ARRAIGNMENT

Dispo: 01/03/2005 REJ - INSUF EVID

Folsom Police Department

46 Natoma St, Folsom, CA 95630

Report Date 12/30/2004 01:40

Case # 01-04-006737

INCIDENT

Case #	Report Date	Occurred From	Occurred To	Report Type
01-04-006737	12/30/2004 01:40	12/29/2004 11:40	12/30/2004 01:40	Original

Dept. Classification	Case Status	Case Status Date	Cleared
SPOUSAL ABUSE	CLEARED BY ARREST	01/04/2005	

Location Information
000000 DR FOLSOM, CA 95630

Day of Week : THURSDAY
Send Report To: : ADULT DA
Location Type : RESIDENCE
Beat Assignment : 4
Alcohol Related : NO

Drug Related : NO
Total Damaged Property Value : $0.00
Total Stolen Property Value : $0.00
Total Recovered Property Value : $0.00

OFFENSE 1

State UCR Classification		Attempted/Committed
ASSAULT SIMPLE		COMMITTED
Statute/Ordinance	**Location Type**	**Disposition Date**
273.5 PC	RESIDENCE	12/30/2004

Federal Classification : ASSAULT SIMPLE
Weapon 1 : HANDS/FISTS/FEET
How Entry Made : UNKNOWN-N/A
Forced Entry : NO

Structure Occupancy : OCCUPIED
Felony/Misdemeanor : FELONY
Offense Status : CLEARED BY ARREST - ADULT

OFFENSE 2

State UCR Classification		Attempted/Committed
DOMESTIC VIOLENCE (STATE)		COMMITTED
Statute/Ordinance	**Location Type**	**Disposition Date**
13700 PC	RESIDENCE	12/30/2004

Federal Classification : DOMESTIC VIOLENCE (STATE)
Weapon 1 : HANDS/FISTS/FEET
How Entry Made : DOOR-FRONT

Forced Entry : NO
Structure Occupancy : OCCUPIED
Offense Status : CLEARED BY ARREST - ADULT

PERSON 1

Person Type	Business/Person Name			Business Phone
VICTIM	VI-1			
Home Phone	**Person Address**			**Map Reference**
	*			
Other Phone	**Employer Address**			**Map Reference**
Race	**Sex**	**SSN**	**DL Exp. Date**	**DL Number**
OTHER	Female			*
Birth Date	**Birth Location**			
[redacted]				

Age : 028
DL State : CA

PERSON 2

Person Type	Business/Person Name			Business Phone
SUSP/ARST	Guru Charan			(916) 356-4652
Home Phone	**Person Address**			**Map Reference**
[redacted]	[redacted] Dolan CT FOLSOM, CA 95630			
Other Phone	**Employer Address**			**Map Reference**
	1900 Prairie City RD FOLSOM, CA 95630			
Race	**Sex**	**SSN**	**DL Exp. Date**	**DL Number**
OTHER	Male			[redacted]
Birth Date	**Birth Location**			
[redacted]				

Age : 028
DL State : CA

Employer : INTEL

Reporting Officer	Department	Report Status:
LOUIS EDGAR WRIGHT (1960)	FOLSOM POLICE DEPARTMENT	Approved
Officer Name		**Date/Time**
SCHANTZ, TYRON		12/30/2004 09:55
Sergeant	**Department**	**Date / Time**
CHARLES ROGERS (1310)	FOLSOM POLICE DEPARTMENT	01/04/2005 12:33

Superior Court of California

720 Ninth Street, Sacramento CA 95814
Criminal Division
Criminal Records
(916) 874-5664

Local Criminal Record Search Response Form

TO: *GURU CHARAN* DATE: *08/16/06*

SUBJECT: *GURU CHARAN*

DOB: [redacted] SSN: [redacted] O/I:

We have received your request for a Sacramento County criminal record search on the above named subject. We have searched our local automated system, which contains criminal records from 1989 to the present. Case information is not available on purged/destroyed records. Use of this information is the receiver's responsibility. The information provided is for Sacramento County arrests only. We do not provide arrest information for other California counties, the Federal Courts, or other states.

☐ This is the case number(s) for an individual based upon the exact criteria submitted. Positive identification cannot be made because the Court is unable to perform fingerprint comparisons.

☐ If you would like copies of the court file(s), please submit a written request for the copies, including the case number(s) previously listed. Include a check with the words "NOT TO EXCEED $25.00" to cover the initial cost of the copies. Please indicate if you would like the copies certified. Send the completed request to the attention of "Certified Copy Unit" at the address listed above. Copies are 50 cents per page. Certifications are $15.00 per case. Record search $15.00 per name. Exemplification $20.00 per case. Please enclose a self-addressed, stamped envelope of appropriate size.

☐ You have submitted a check or money order exceeding the actual fees. A refund for the overage will be mailed in approximately six weeks. Your copy of the receipt is enclosed.

☐ We have searched our local automated system and are unable to locate criminal record information on an individual that meets the criteria that you submitted.

☐ We are unable to provided research for any automated information prior to 1989. The criminal indexes prior to 1989 are unavailable on the public microfiche located in the Records Unit.

☐ Additional information is necessary to process your request. Please re-submit your request with the following information: _____

☒ Other: *NO CHARGES ON ARREST 12/30/04 FOR PC. 273.5, PC 13700*

CR- 278 (revised 01/01/06) Original – Requestor Yellow - Court

Mark I. Sedar

From: V. Stallings <stallingsv@gmail.com>
Sent: Tuesday, November 24, 2020 3:35 PM
To: Mark I. Sedar
Subject: Re: BIOLOGIC LLC. Request forms for Application Approval
Attachments: image001.jpg

Mark,

The only employee that will be handling the drugs daily is myself Vanessa Stallings.

The Officer of Biologic LLC. is Guru Charan.

The Director of Biologic LLC. is Michael Ping.

If I need to place this on a separate form as an attachment please let me know.
Thank you.

Vanessa

On Tue, Nov 24, 2020, 3:21 PM Mark I. Sedar <msedar@pharmacy.nv.gov> wrote:

Hi Vanessa,

Thank you for the information. Please note that I will need additional information to complete the review process of the application.

- A list of employees who handle drugs daily
- A list of Officers and Directors of the company.

Thank you,

Mark Sedar

Chief Operating Officer

Nevada State Board of Pharmacy

(775) 850-1440

msedar@pharmacy.nv.gov



This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: V. Stallings <stallingsv@gmail.com>
Sent: Tuesday, November 24, 2020 2:59 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: Re: BIOLOGIC LLC. Request forms for Application Approval

Good afternoon,

My name is Vanessa Stallings and we spoke on the phone 11/12/20.

Here are the documents you requested that are needed for the application process. If there is any other information you need please let me know. Thank you for your time.

Vanessa Stallings

VANESSA STALLINGS
North Las Vegas NV, 89086
stallingsv@gmail.com
[redacted]

PROFESSIONAL OBJECTIVE

To secure a position within an organization where I can utilize my exceptional highly organized results driven skills, resourcefulness, self-directed passion to maximize administrative, supervision, and management skills to ensure the growth of the company.

PROFESSIONAL SUMMARY

- A highly resourceful, flexible, innovative, and enthusiastic individual; possesses a considerable amount of knowledge regarding administrative and office procedures.
- An experienced Administrative Assistant; technically proficient and computer literate in MS Word, Office, Excel, Power Point, etc.; advanced experience with automated data bases used in records management, ordering, tracking, receiving, distributing and managing financial assets.
- A quick learner that can absorb new ideas and is experienced with coordinating, planning and organizing a wide range of administrative activities.

RELEVANT EXPERIENCE

Administrative Assistant:

- Proven track record of meeting deadlines, being highly organized, and efficiently prioritizing and handling multiple tasks.
- Pays attention to detail and accuracy, goal oriented team player, flexibility with hours, and excellent attendance.
- Records manager; maintaining an electronic and hard copy filing system. Effective organizational skills.

Office Manager:

- Maintained awareness of advances in medicine, computerized health diagnostics, and treatment equipment. Data processing, government regulations, changes in health insurances and or financing options.
- Planned, implemented, and administered programs and services in a health care or medical facility to include personnel administration, training and coordination of medical, nursing and associates.
- Able to use knowledgeable relevant information and individual judgment to determine whether events or processes comply with laws, regulations and standards.

Pharmacy Office Manager:

- Maintained communication between governing boards, medical staff, and the department heads by attending board meetings, and coordinating interdepartmental functioning.
- Managed changes in integrated health care delivery systems, such as work restructuring, technological innovations, and shifts in the focus of care.
- Maintain and review computerized records management systems to store and process data such as drug analysis and statistics and other information to produce reports.

OTC Manager/ Lead Pharmacy Technician:

- Prepare reports to inform management of the status and implementation of plans and services, and quality initiatives.
- Knowledge of marketing strategy and tactics, sales techniques, and sales control systems.
- Monitored and maintained staff assignments, work schedules, as well as directed and conducted recruitment, hiring and training of personnel.

VANESSA STALLINGS
North Las Vegas NV, 89086
stallingsv@gmail.com
[redacted]

EMPLOYMENT HISTORY

2019-2020 Portofino Labs Inc. Contractor/ Pharmacy Administrative
2016-2019 Access Healthcare Lead Pharmacy Technician
2018-2019 Asembia Inc. Pharmacy Technician / Resolution Expert
2016-2017 Meditech Pharmacy Inc. Office Mgr. /Pharmacy Technician
2008-2016 Michael O'Callaghan Fed. Hosp. Sup. Pharm Tech /Admin. Assist
2007-2008 Ariana's Cosmetic Surgery Ctr. Office Mgr./Pharmacy Technician
2003-2007 Walmart Inc. OTC Mgr./Lead Pharmacy Technician

RELATED SKILLS AND EDUCATION

Microsoft Office Software/Applications (Excel,Office, Publisher,PowerPoint,Outlook)
Quickbooks Accounting Software
Electronic Records Management
Scheduling Software
CPR Instructor/AED Instructor - (American Red Cross) 2022
Misys Healthcare Systems and Microsys Micro MD
McKesson Medisoft software and Cardinal Health Pyxis II Safe
Pharmacy Management Software
DMHRSi (Government Software)
AHLTA or Enterprise Wide Referral and Authorization System (EWRAS)
CHCS (Composite Health care System) & ADS (Ambulatory Data System)
VISTA (Government Computer Program)
DEERS (Government Computer Program)
Pharmacology Practices – (Heritage College; Las Vegas, Nevada)
Healthcare Management -BA- (Fayetteville Technical Community College of NC) Long Term Health Care Management – (Fayetteville Technical Community College of NC)
Medical Billing Practices – (Fayetteville Technical Community College of NC)
ICD-10/CPT Coding – (Fayetteville Technical Community College of NC)
Practical Nursing - AA- (Fayetteville Technical Community College of NC)
Medication Administration – (Fayetteville Technical Community College of NC)
Computerized Bookkeeping and Accounting – (Alaska Business College)

REFERENCES UPON REQUEST

Michael Ping

[redacted]

2020 - Present	Managing Director, Galt Pharmaceuticals Manages a unique pharmaceutical company that has found a better way to enhance the quality of life of patients with products that meet unmet clinical needs.
2011 - 2019	CEO, Blackhawk Investment Corp. Peer to Peer Lending for Real Estate. Developed and operated an internet platform which match private and institutional funds for real estate investment purposes. Overseen the strategic direction and operation of investments. Launched and developed business with a focus on improving the quality of life and well-being of consumers.
2002 – 2011	CEO, Millennium Health, Inc. Millennium Health dba. eBiocare.com was acquired by Curative Health, in 2001 as the first web-based specialty pharmacy serving consumers with life-long rare chronic conditions.
1993 – 1995	Regional Sales Mgr., Quantum Health Resources Provided a complete spectrum of home health and pharmacy services to patients with rare chronic conditions in the Northern California and Hawaii regions.
1991 – 1993	Territory Manager, Baxter Healthcare, Biotech Group Baxter Biotech developed and manufactured specialty biotech drugs. Responsible for territory sales, including hospital accounts.
1988 – 1991	Pharmaceutical Sales Representative, Berlex Lab (Div. of Schering A.G.) An integrated specialty pharmaceutical company who provides medications to patients and healthcare providers. Berlex markets some 20 products.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 7901041892

Application/License No. _____

BioLogic LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 593 Caribbean Palm Dr, Las Vegas, NV 89138 (Address of Applicant/Principal), as PRINCIPAL, and Nationwide Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1100 Locust St Dept 2006 Des Moines, IA 50391 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/23/2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of October, 2020.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Jeremy John Crawford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

SEAL

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS THAT

Nationwide Mutual Insurance Company, an Ohio corporation

hereinafter referred to severally as the "Company" and collectively as "the Companies" does hereby make, constitute and appoint:

JEREMY JOHN CRAWFORD, MICHAEL D WILLIAMS

each in their individual capacity, its true and lawful attorney-in-fact, with full power and authority to sign, seal, and execute on its behalf any and all bonds and undertakings, and other obligatory instruments of similar nature, in penalties not exceeding the sum of

TEN MILLION AND NO/100 DOLLARS ($10,000,000.00)

and to bind the Company thereby, as fully and to the same extent as if such instruments were signed by the duly authorized officers of the Company; and all acts of said Attorney pursuant to the authority given are hereby ratified and confirmed.

This power of attorney is made and executed pursuant to and by authority of the following resolution duly adopted by the board of directors of the Company:

"RESOLVED, that the president, or any vice president be, and each hereby is, authorized and empowered to appoint attorneys-in-fact of the Company, and to authorize them to execute and deliver on behalf of the Company any and all bonds, forms, applications, memorandums, undertakings, recognizances, transfers, contracts of indemnity, policies, contracts guaranteeing the fidelity of persons holding positions of public or private trust, and other writings obligatory in nature that the business of the Company may require; and to modify or revoke, with or without cause, any such appointment or authority, provided, however, that the authority granted hereby shall in no way limit the authority of other duly authorized agents to sign and countersign any of said documents on behalf of the Company."

"RESOLVED FURTHER, that such attorneys-in-fact shall have full power and authority to execute and deliver any and all such documents and to bind the Company subject to the terms and limitations of the power of attorney issued to them, and to affix the seal of the Company thereto; provided, however, that said seal shall not be necessary for the validity of any such documents."

This power of attorney is signed and sealed under and by the following bylaws duly adopted by the board of directors of the Company:

Execution of Instruments. Any vice president, any assistant secretary or any assistant treasurer shall have the power and authority to sign or attest all approved documents, instruments, contracts, or other papers in connection with the operation of the business of the company in addition to the chairman of the board, the chief executive officer, president, treasurer or secretary; provided, however, the signature of any of them may be printed, engraved, or stamped on any approved document, contract, instrument, or other papers of the Company.

IN WITNESS WHEREOF, the Company has caused this instrument to be sealed and duly attested by the signature of its officer the 27th day of February, 2019.

Antonio C. Albanese, Vice President of Nationwide Mutual Insurance Company

SEAL

ACKNOWLEDGMENT

STATE OF NEW YORK, COUNTY OF NEW YORK: ss

On this 27th day of February, 2019, before me came the above-named officer for the Company aforesaid, to me personally known to be the officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, deposes and says, that he is the officer of the Company aforesaid, that the seal affixed hereto is the corporate seal of said Company, and the said corporate seal and his signature were duly affixed and subscribed to said instrument by the authority and direction of said Company.

Suzanne C. Dello
Notary Public, State of New York
No. 02DE6126849
Qualified in Westchester County
Commission Expires September 16, 2021

Notary Public
My Commission Expires
September 16, 2021

CERTIFICATE

I, Laura B. Guy, Assistant Secretary of the Company, do hereby certify that the foregoing is a full, true and correct copy of the original power of attorney issued by the Company; that the resolution included therein is a true and correct transcript from the minutes of the meetings of the boards of directors and the same has not been revoked or amended in any manner; that said Antonio C. Albanese was on the date of the execution of the foregoing power of attorney the duly elected officer of the Company, and the corporate seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority of said board of directors; and the foregoing power of attorney is still in full force and effect.

IN WITNESS WHEREOF, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of said Company this 23rd day of October, 2020.

SEAL

Laura B. Guy

Assistant Secretary

BDJ 1(02-19)00

Acknowledgment of Surety

State of Minnesota
County of Anoka

On this 23rd day of October, 2020 before me personally appeared **Jeremy John Crawford** who acknowledged that he or she is the attorney in fact who is authorized to sign on behalf of **Nationwide Mutual Insurance Company** (surety company), the foregoing instrument, and he thereupon duly acknowledged to me that he executed the same.

JONATHAN C. KRASKEY
Notary Public-Minnesota
My Commission Expires Jan 31, 2025

Notary Public

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for

BioLogic, LLC

Organizational Documents on File	Filing Date
Certificate of Correction	11/06/2020
Amended List	10/09/2020

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, BioLogic, LLC, as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 09/18/2020, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/19/2020

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202011191223438
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

11/18/2020

Work Order Item Number:	W2020111600851-942116
Filing Number:	20201049859
Filing Type:	Certificate of Correction
Filing Date/Time:	11/6/2020 10:00:00 AM
Filing Page(s):	1

Indexed Entity Information:

Entity ID: E9205142020-7 **Entity Name:** BioLogic, LLC

Entity Status: Active **Expiration Date:** None

Commercial Registered Agent
JEFFREY J WHITEHEAD, ESQ.
6980 O'BANNON DR., LAS VEGAS, NV 89117, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date 10/23/2020

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for ~~BIOLOGIC, LLC~~ V.S WHOLESALER
Nature of Pharmacy or Wholesaler

BIOLOGIC, LLC 8420 S. Eastern Ave STE 101 Las Vegas, NV 89123
Name and Address of Business for Which Designated Representative is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Stallings (Last Name) | Vanessa (First Name) | Rene' (Middle Name)

Robinson
Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] John Bery Court (Present Residence Address-Street or RFD) | North Las Vegas (City) | NV 89086 (State/Zip)

Dates
Present Business Address | City | State/Zip

Pharmacy Technician (Present Position with the Pharmacy or Wholesaler) Dates 9/14/2020

Phone: Residence [redacted]

[redacted] (Date of Birth) | Anchorage, Alaska (Place of Birth (City, County, State)) | Business N/A

51 Y.O. (Age) | [redacted] (Social Security Number or ITIN) | Female (Sex)

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Dark Brown	Blk	Brown	145 lbs	Small	5'5

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No If alien, registration No N/A

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single Married Separated Divorced Widowed Engaged

Applicant's initial V.S.

A. **Current Marriage** 2004 (Date) Fayetteville, N.C. (City, County and State)

Spouse's full name (Maiden) Darcy Da Costa Stallings SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth New York

Resident address [redacted] (Street) John Bery Court (City) North Las Vegas (State) Nv (Zip) 89086

Telephone: Residence [redacted] Business N/A

Spouse's employer Veterans Administration Occupation Systems Redesign Engineer

Address of employer 6900 N. Decos Rd (Street), North Las Vegas (City), Nv (State) 89086 (Zip)

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
N/A				
N/A				
N/A				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
N/A					
N/A					
N/A					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Ashley Stallings	[redacted]	Az	[redacted] S. Nellis Blvd 89121 Apt [redacted]
Ryan Stallings		Az	[redacted] S. Nellis Blvd [redacted] 89121
John Robinson		Ak	[redacted] Goodwill St. 89106

B. Child Support Information:

Please mark the appropriate response:

- ☑ I am not subject to a court order for the support of child.
- ☐ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial V.D.

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name N/A

Address N/A

Contact person N/A

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Willie James Robinson	[redacted]	[redacted] Gentsi MD #101 LV NV 89084	(Retired)
Mother	Arvella Genice Thomas	[redacted]	[redacted] old Squaw Lp, Wasilla Ak 99654	(Retired)
Father-in-Law	N/A	N/A	N/A	
Mother-in-Law	Gussie Stallings		[redacted] Sea Mtn Hwy Little River S.C.	(deceased)

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Aaron Robinson	[redacted]	[redacted] Elmore Rd Anchorage, Alaska 99516	Fire fighter
Spouse Frances Robinson		[redacted] Elmore Rd Anchorage, AK 99516	Fire Fighter
Jalmar Robinson		[redacted] NOBLE POINT DR. Anchorage, Alaska 99516	Ak. State Employee
Spouse Julie Robinson		[redacted] NOBLE POINT DR. Anchorage, Alaska 99516	Student
Roy Matthews III		[redacted] old Squaw Lp Wasilla, Alaska 99654	State Employee
Spouse Suzy Matthews		[redacted] old Squaw loop Wasilla Alask 99654	Housewife
Spouse			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	Rabbit Creek El.	Anch. Ak	9/1980 – 1982	(Yes) No
High School	S.A.V.E I H.S.	Anch. AK	9/1986-2/1987	(Yes) No
College University	Fayetteville Tech Comm. College	Fay. N.C.	9/2003-1/2005	(Yes) No
Other	Heritage College	Las Vegas, NV	2/2001 – 1/2008	(Yes) No

Type of degree obtained, if any Health Care Administration

College or university where obtained Fayetteville Tech Comm College

Applicant's initial V.b.

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes → (No) →

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes → (No) → If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes → (No) →

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes → (No) → If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
N/A			N/A		
N/A			N/A		
N/A			N/A		

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes → (No) → If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes → (No) →

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes → (No) →

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes → (No) →

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes → (No) →
If yes, when?_____ city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes → (No) →
If yes when?_____ city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes → (No) →
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				
N/A				
N/A				

Applicant's initial V. S.

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ← (No) ← (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ← (No) ← If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A	N/A	N/A
N/A	N/A	N/A
N/A	N/A	N/A
	N/A	

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2020 - 1/2010	1808 John Bevy Ct	NLV, Nv 89	Nv
1/2010 - 8/2005	5349 Santa Fe Height	NLV	Nv
8/2005 - 1/2001	11 Holland St	Ft Bragg	N.C.
1/2001 - 11/1997	101 Wyatt Court	Raeford	N.C.
11/1997 - 11/1996	16828 Kayuga st	Victorville	Ca
11/1996 - 9/1993	2321 Timothy Lane	Anchorage	AK

Applicant's initial V. S.

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
9/2016 1/2019	Aacess Health Care & Recruitement 5025 S. Eastern Ave #25 LV, NV 89119	5,760
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Tech.	Problem solving, organizational skills Dispensing meds to hospital, long term facility Prepare Prescription labels, Compounding, IV's	ESOSA

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
10/2018 4/2019	Asembia, LLC 3844 Meadows Lane 89107	1,920
Title	**Description of Duties**	**Name of Supervisor**
Pharmacy Tech.	Record keeping HIPAA Compliance; data entry, Insurance Verif. Payment processing, time mgmt, Computers	Diana Williams

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
9/2008 9/2016	Mike O'Callaghan Fed Hospital 4700 Las Vegas Blvd N. 89191	15,360
Title	**Description of Duties**	**Name of Supervisor**
Lead Pharm Tech	Dispensing meds to the units, Problem solving, Prepare labels time mgmt, IV prep + Sterilization, Compounding, Communication	Eric Shalita

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
9/2006 9/2008	Nathan Adelson Hospice 4141 Swenson Las Vegas NV 89119	1,920
Title	**Description of Duties**	**Name of Supervisor**
Lead Pharm. Tech	Work Closely with Pharmacist. IV dispensing under aseptic or sterile conditions; Record keeping data entry	Linda Hollis

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
8/2005 8/2006	Walmart Inc 6570 E. Lake Mead Blvd Las Vegas, Nv 89156	1,920
Title	**Description of Duties**	**Name of Supervisor**
OTC mgr/Lead Pharmaty Tech	Prepare and fill prescriptions, manage inventory, Ins. Verification, data entry	Kit Nuygen

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial V.S.

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Cindy Armstrong	[redacted]	Kinnear St. Kelso,	WA	98626	[redacted]	35 yrs.
Home						
Employer AK USA Fed C.U.	Business					
Name Denise Washinaton	[redacted]	Carlson Blvd Richmond	Ca	94804	[redacted]	30 yrs
Home						
Employer Amtrak	Business					
Name Tiffany Murphy	[redacted]	Harmonize ct Lv, Las Vegas,	NV	89131	[redacted]	12 yrs
Home						
Employer Veteran Admin	Business					
Name Vache Brooks	[redacted]	Fiscus Loop (Fort Huachuca, AZ) Sierra Vista,	AZ	85635	[redacted]	20yrs.
Home						
Employer U.S. Military	Business					
Name Roxane Sugameli	[redacted]	Amber Valley Ln Las Vegas,	NV	89134	[redacted]	25 yrs.
Home						
Employer CIK Cty School Dist	Business					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes — (No) —

If yes, state type, where and years held

N/A

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes — (No) —
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes — (No) —

N/A

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes — (No) —

N/A

If yes to the above, state where, when and for what reason:

Applicant's initial V. S.

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ~ (No) ~

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ~ (No) ~

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ~ (No) ~

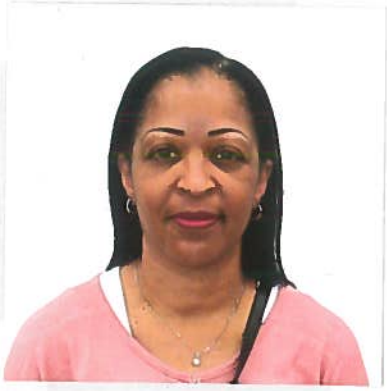
17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes ~ (No) ~

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ~ (No) ~

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? (Yes) ~ No ~

20. Will you be employed fulltime with the pharmacy or wholesaler? (Yes) ~ No ~

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? (Yes) ~ No ~



Date of photograph 9/25/2020

Applicant's initial V. A.

STATE OF Nevada
ss.

COUNTY OF Clark

I, Vanessa Rene Stallings, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Vanessa Rene Stallings
Original Signature of Applicant

Subscribed and Sworn to before me this 25th day of September, 2020.

Notary Public

CASSANDRA AMAYA HAMM
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-29-2023
Certificate No: 19-9614-01

(seal)

Applicant's initial V. S.

ADDITIONAL INFORMATION

N/A

Applicant's initial V. S.

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

2591

Date 10/23/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for BIOLOGIC LLC
Nature of License

BIOLOGIC, LLC 8420 S. EASTERN AVE STE 101 Las Vegas NV 89123
Name and Address of Establishment for Which License Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

CHARAN	GURU	N/A
Last Name	First Name	Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] CARIBBEAN PALM DR.	LAS VEGAS	NV 89138
Present Residence Address-Street or RFD	City	State/Zip

8420 SOUTH EASTERN AVE Dates	LAS VEGAS	NV 89123
Present Business Address	City	State/Zip

~~N/A~~ 0 Dates	Phone: Residence [redacted]
Occupation	Business 702-385-6488

[redacted]	SHIMOGA, INDIA
Date of Birth	Place of Birth (City, County, State)

44 YEARS	[redacted]	MALE
Age	Social Security Number	Sex

BROWN	BLACK	MEDIUM	230 lbs	MEDIUM	6' 0"
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics MOLE on LEFT HIP

Are you a citizen of the United States? Yes ☒ No ☐ If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☐ Married ☐ Separated ☐ Divorced ☒ Widowed ☐ Engaged ☐

Applicant's initial

A. **Current Marriage** — NA —
Date City, County and State

Spouse's full name (Maiden) S.S. No — NA —

Date of Birth — NA — Place of Birth — NA —

Resident address
Street City State Zip

Telephone: Residence — NA — Business — NA —

Spouse's employer — NA — Occupation — NA —

Address of employer — NA —
Street City State Zip

B. Previous Marriages: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
ARCHANA PRAKASH	07/20/2005	12/27/1999	DIVORCE	SACRAMENTO, CA
APARNA KRISHNAPPA	11/25/2012	8/9/2009	DIVORCE	COOK COUNTY, IL

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
ARCHANA PRAKASH	[redacted] ROWE CT	FREMONT	CA	94536	[redacted]
APARNA KRISHNAPPA	[redacted] PACER TR	S. BARRINGTON	IL	60010	[redacted]

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
Aarya CHARAN	[redacted]	SACRAMENTO, CA	[redacted] ROWE CT FREMONT CA 94536
JAIDEN CHARAN		HOFFMAN ESTATES, IL	[redacted] PACER TRAIL, S. BARRINGTON IL 60010

B. Child Support Information:

Please mark the appropriate response:

☒ I am not subject to a court order for the support of child.

☒ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or

☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name ILLINOIS STATE CHILD SUPPORT SERVICES

Address P.O. BOX 5921 CAROL STREAM IL 60197-5921

Contact person — NA —

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Y.L. SHASHIDHAR	[redacted]	[redacted] MAIN 11th CROSS JAYANAGAR 2nd BLOCK BANGALORE INDIA 560011	— 11 —
Mother	VANAJA SHASHIDHAR			
Father-in-Law	— NA —			
Mother-in-Law	— NA —			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

Name (Maiden)	Birth Date	Address	Occupation
Spouse			
Spouse	N/A		
Spouse			
Spouse			

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School		INDIA		Yes ☒ No ☐
High School	VIJAYA HIGH SCHOOL	INDIA	1990-94	Yes ☒ No ☐
College University	BANGALORE UNIV	INDIA	1994-98	Yes ☒ No ☐
Other	UNIV. OF VIRGINIA	CHARLOTTESVILLE, VA	2005-07	Yes ☒ No ☐

Type of degree obtained, if any B.S ; M.S ; MBA

College or university where obtained BANGALORE UNIV ; WESTERN MICHIGAN UNIV ; UNIV OF VIRGINIA

Applicant's initial

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes ☐ No ☒

Branch N/A Date of entry-active service N/A

Date of separation N/A Type of discharge N/A

Rating at separation N/A Serial number N/A

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes ☐ No ☐ If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes ☐ No ☒

County N/A State N/A Date registered N/A

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes ☒ No ☐ If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
12/29/2004	28 YRS	DOMESTIC VIOLENCE	FOLSOM, CA	CHARGES DROPPED	FOLSOM PD / SACRAMENTO COUNTY

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes ☐ No ☒ If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes ☐ No ☒

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☒

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes ☐ No ☒

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes ☐ No ☒
If yes, when? city, county and state

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes ☐ No ☒
If yes when? city, county and state

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes ☐ No ☒
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
N/A				

Applicant's initial

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ☐ No ☒ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
N/A				

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ☐ No ☒ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
N/A		

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
08/20 to date	[redacted] CARIBBEAN PALM DR	LAS VEGAS	NV 89138
06/16 to 08/20	34480 VALLEY OAKS LOOP	UNION CITY	CA 94587
11/13 to 06/16	24 UNION SQ	UNION CITY	CA 94587
11/12 to 11/13	21 W. 10th ST	KANSAS CITY	MO 64105
04/09 to 11/12	3 PACER TR.	S. BARRINGTON	IL 60010
08/07 to 04/09	ONE BRYANT PARK #2025	NEW YORK	NY 10036
08/05 to 07/07	1546 WATER OAK CT	CHARLOTTESVILLE	VA 22903
04/01 to 08/05	971 DOLAN CT	FOLSOM	CA 95630
12/98 to 04/01	125 S KENDALL DR #201	KALAMAZOO	MI 49008
04/82 to 12/98	14/2 BYRASANDRA MA RD	BANGALORE	INDIA 560011

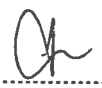
Applicant's initial .....

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
08/2020	VALLEY OAKS MEDICAL GROUP	NA
Title	**Description of Duties**	**Name of Supervisor**
CEO	MANAGE MEDICAL CLINICS	NA
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
10/2017	WELLS FARGO BANK, SAN FRANCISCO, CA	ENTREPRENEURIAL
Title	**Description of Duties**	**Name of Supervisor**
SR VP	CORPORATE STRATEGY	NAREN NATH
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
11/2012	H&R BLOCK, KANSAS CITY MO	MOVE TO CALIFORNIA
Title	**Description of Duties**	**Name of Supervisor**
VICE PRES.	CORPORATE STRATEGY	KUSH SAXENA
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
08/2009	DISCOVER CARDS, RIVERWOODS, IL	BETTER OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
DIRECTOR	CORPORATE STRATEGY	NICK BROWN
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
08/2007	BANK OF AMERICA, NEW YORK, NY	BETTER OPPORTUNITY
Title	**Description of Duties**	**Name of Supervisor**
ASSOCIATE	INVESTMENT BANKING	TONY BEAMS
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
04/2000	INTEL CORP, FOLSOM CA	GRAD SCHOOL
Title	**Description of Duties**	**Name of Supervisor**
ENGINEER	SOFTWARE ENGINEERING	MARCUS GRINDSTAFF
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
Title	**Description of Duties**	**Name of Supervisor**
Month and Year	**Name/Mailing Address of Employer/Business**	**Reason for Leaving**
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial 

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name AMIT AGGARWAL	Home [redacted]	MADIERA LN	BUFFALO GROVE	IL 60089	[redacted]	10+
Employer SELF EMPLOYED	Business	E-COMMERCE				
Name NEIL AHUJA	Home [redacted]	MISSION ST #1802	SAN FRANCISCO	CA [redacted]		1ST
Employer CRICKET HEALTH	Business	HEALTHCARE				
Name DAN LEONARD	Home [redacted]	FARRAGUT RD #2C	NEW YORK,	NY [redacted]		10+
Employer WELLS FARGO	Business	FINANCE				
Name MADHU SEN	Home [redacted]	WARREN ST #09	JERSEY CITY	NJ [redacted]		10+
Employer MASTERCARD	Business	BUSINESS				
Name KUSH SAXENA	Home [redacted]	BROADWAY	NEW YORK	NY [redacted]		10+
Employer MASTERCARD	Business	EXECUTIVE				

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ☐ No ☒
If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users
- N/A -			
- N/A -			
- N/A -			

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes ☐ No ☒
If yes, state type, where and years held

N/A

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ☐ No ☒
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

N/A

Applicant's initial [signature]

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes ☐ No ☒

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes ☐ No ☒

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes ☐ No ☒

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes ☐ No ☒

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes ☐ No ☒

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes ☐ No ☒



Date of photograph 9/21/2020

Applicant's initial

STATE OF Nevada
ss.
COUNTY OF Clark

I, GURU CHARAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 22 day of September 2020

Notary Public

DENISE HARTGROVE
Notary Public - State of Nevada
County of Clark
APPT. NO. 18-4224-1
My App. Expires Oct. 8, 2022

(seal)

Applicant's initial

ADDITIONAL INFORMATION

- N/A -

Applicant's initial

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

Date 10/23/20

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for WHOLESALER
Nature of License

BIOLOGIC ~~HEALTH RESOURCES~~ MP, LLC 8420 S EASTERN AVE. STE 101, LAS VEGAS, NV 89123
Name and Address of Establishment for Which License Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

PING | MICHAEL | DANIEL
Last Name | First Name | Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] W HOMESTEAD CT | CHANDLER | AZ | 85286
Present Residence Address-Street or RFD | City | State/Zip

6980 O'BANNON DR (2020) | LAS VEGAS | NV | 89117
Present Business Address (Dates) | City | State/Zip

DIRECTOR | Dates 2020
Occupation

Phone: Residence [redacted]

[redacted] | SAN FRANCISCO, CA | Business 650-714-6577
Date of Birth | Place of Birth (City, County, State)

58 | [redacted] | MALE
Age | Social Security Number or ITIN | Sex

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
BLK	BLK	TAN	159 LBS	6000	5'10"

Scars, tattoos or distinguishing marks and/or characteristics N/A

Are you a citizen of the United States? (Yes) No — If alien, registration No N/A

If naturalized, certificate No N/A Date N/A

Place N/A (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single — Married — Separated — (Divorced) — Widowed — Engaged —

Applicant's initial MP

A. Current Marriage N/A
Date City, County and State

Spouse's full name (Maiden) _____ SS# or ITIN _____

Date of Birth _____ Place of Birth _____

Resident address _____
Street City State Zip

Telephone: Residence _____ Business _____

Spouse's employer _____ Occupation _____

Address of employer _____
Street City State Zip

B. **Previous Marriages:** If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
KIMBERLY ALLISON	6/2020	11/2018 AZ	MUTUAL CONSENT DECREE	MARICOPA, AZ
JUNE PING	10/2007	8/~~1993~~ CA	DISSOLUTION	SAN MATEO, CA

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
KIM ALLISON	[redacted] W. HOMESTEAD CT.	CHANDLER,	AZ	85286	[redacted]
JUNE PING	[redacted] W. ASTER DR.,	CHANDLER,	AZ	85248	

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address
TAYLOR PING	[redacted]	REDWOOD CITY, CA	[redacted] W ASTER DR., CHANDLER, AZ 85248
KAELSTEN PING		REDWOOD CITY, CA	[redacted] W ASTER DR, CHANDLER, AZ 85248

B. Child Support Information:

Please mark the appropriate response:

- ☐ I am not subject to a court order for the support of child.
- ☑ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ☐ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial MP

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name DIVISION OF CHILD SUPPORT (DCSS)

Address PO BOX 40458, PHOENIX, AZ 85067-0458

Contact person DCSS LEADERSHIP TEAM

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	DAN PING	[redacted]	LONDON LN, BELMONT, CA 94002	1/1930 RETIRED BUSINESS MAN
Mother	SUE PING	[redacted]	LONDON LN, BELMONT, CA 94002	8/1938 RETIRED X-RAY TECH
Father-in-Law	N/A			
Mother-in-Law	N/A			

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	KATHY PING	[redacted]	BONITO AVE., BURLINGAME, CA 94010	RETIRED BUSINESS
Spouse	SIMON HEAP - CONSULTANT	N/A	(SAME AS ABOVE)	
	CAROLYNN PING	[redacted]	REDWOOD CITY, CA	HEALTHCARE EXECUTIVE
Spouse				
	MARILYN PING	[redacted]	SUNFISH CT., FOSTER CITY, CA 94404	ACCOUNTING
Spouse	MATT ALDEN - LOGISTICS MANAGER	N/A	(SAME AS ABOVE)	
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	ROOSEVELT	BURLINGAME, CA	1970-76	(Yes) No
High School	BURLINGAME	BURLINGAME, CA	1976-80	(Yes) No
College University	U.C. DAVIS	DAVIS, CA	1980-86	(Yes) No
Other				Yes No

Type of degree obtained, if any B.A.

College or university where obtained U.C. DAVIS

Applicant's initial AP

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes — (No) —

Branch — N/A — Date of entry-active service _____

Date of separation _____ Type of discharge _____

Rating at separation _____ Serial number _____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? N/A Yes — No — If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? N/A Yes — No —

County _____ State _____ Date registered _____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) (Yes) — No — If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency
8/2015	53	ASSULT	CHANDLER, AZ	DISMISSED 10/2015	CHANDLER PD

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes — (No) — If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes — (No) —

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes — (No) —

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes — (No) —

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes — (No) —
If yes, when? _____ city, county and state _____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes — (No) —
If yes when? _____ city, county and state _____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes — (No) —
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date
— N/A —				

Applicant's initial MD

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
(Yes) ➡ No ➡ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date
DEFENDANT	6/26/2019	CV2019-005548	PHOENIX, MARICOPA, AZ	MEDIATION
RESPONDENT	10/8/2004	2004-1-CV-024306	SANTA CLARA, CA	VACATED
DEFENDANT	4/8/2010	2010-1-CV-168731	SANTA CLARA, CA	CLOSED/INACTIVE

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
(Yes) ➡ No ➡ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy
BIOLOGIC HEALTH	LLC	6/10/1997
BLACKHAWK	C CORP	3/23/2017

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
9/2018 – CURRENT	[redacted] W HOMESTEAD CT.	CHANDLER	AZ
10/2014 - 9/2018	4777 S FULTON RANCH BLVD.	CHANDLER	AZ
8/2010 - 10/2014	1828 FELL ST.	SAN FRANCISCO	CA
12/2008 – 1/2010	25 MOUNTAIN WOOD CT.	HILLSBOROUGH	CA
12/2007 - 12/2008	3029 CANYON DR.	BURLINGAME	CA
3/2006 – 12/2007	1320 MARLBOROUGH RD.	HILLSBOROUGH	CA
2/1999 – 3/2006	1137 HILLSLOPE DR.	LOS ALTOS	CA
3/1995 – 2/1999	844 TALISMAN DR.	SUNNYVALE	CA
1/1993 – 3/1995	412 LAUREL ST.	SAN CARLOS	CA

Applicant's initial MP

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/2020-	HEALTH CONSULTANT 1426 W HOMESTEAD CT. CHANDLER, AZ 85286	N/A
Title	**Description of Duties**	**Name of Supervisor**
DIRECTOR,	HEALTHCARE BUSINESS CONSULTING	N/A

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/2009 - 12/2019	BLACKHAWK INVESTMENTS 4744 S. FULTON RANCH BLVD, CHANDLER AZ 85248	CLOSED BUSINESS
Title	**Description of Duties**	**Name of Supervisor**
CEO	PRIVATE MONEY LENDING TECH	ROBERT WOLFFE -

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
8/2001 - 12/2009	PRIVATE INVESTOR	TO FORM A P2P SOFTWARE CO.
Title	**Description of Duties**	**Name of Supervisor**
DIRECTOR/TRUSTEE	INVEST FAMILY ASSETS	N/A

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
6/1995 - 8/2001	MILLENNIUM HEATH INC, 4677 OLD IRONSIDE DR, SANTA CLARA, CA	SOLD THE COMPANY
Title	**Description of Duties**	**Name of Supervisor**
CEO	DIRECT EXECUTIVE MANAGEMENT	BOARD OF DIRECTORS

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
2/1993 - 6/1995	QUANTUM HEALTH RESOURCES, ALAMEDA, CA	TO GO START MY OWN COMPANY
Title	**Description of Duties**	**Name of Supervisor**
SR. ACCOUNT EXECUTIVE	REVENUE PRODUCTION	JERRY HANSON

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/1990 - 2/1993	BAXTER HEALTHCARE, BIOTECH GROUP, DEERFIELD, IL	RECRUITED TO QUANTUM
Title	**Description of Duties**	**Name of Supervisor**
TERRITORY MANAGER	SALES	JEFF ANDERSON

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
5/1986 - 1/1990	BELLEX LABORATORIES, NEW JERSEY	LEFT FOR BAXTER
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial WP

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name MELLA HAJJAN	Home [redacted]	39TH ST. UNIT 615,	OAKLAND,	CA 94609	[redacted]	10 YRS
Employer SELF	Business	BUSINESS / REAL ESTATE DECOR CONSULTING				
Name STERLING GATEWOOD III	Home [redacted]	W RAY RD., SUITE 4-250,	CHANDLER,	AZ 85226	[redacted]	5 YRS
Employer FINANCE OF AMERICA	Business	6900 E CAMELBACK RD, SUITE 240,	SCOTTSDALE,	AZ 85251		
Name LEAMON CREEMS	Home [redacted]	N COBBLESTONE RD,	TUCSON,	AZ 85718	[redacted]	35 YRS
Employer STRATGROW	Business	1661 N SWAN RD, STE 208,	TUCSON,	AZ 85712		
Name WESTLY ANDERSON	Home [redacted]	N POTSDAM, PMB 1978,	SIOUX FALLS,	SD 57104	[redacted]	5 YRS
Employer SELF/REALTOR	Business	3916 N POTSDAM, PMB 1978,	SIOUX FALLS,	SD 57104		
Name MIKE WARGEL	Home [redacted]	E CAROB DR.,	CHANDLER,	AZ 85286	[redacted]	5 YRS
Employer INTERVISION 1099 CONSULTANT	Business	1817 E CAROB DR.,	CHANDLER,	AZ 85286		

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ~~No~~

If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
~~Accountant~~	Pilot	Sports promoter	Trainer or manager	Educator

Yes ~~No~~

If yes, state type, where and years held

CALIFORNIA BOARD OF PHARMACY WHOLESALERS EXEMPTEE LICENSE 1995-1997

FINRA SERIES 3 LICENSE IN CALIFORNIA 1986-87

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes ~~No~~

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

Applicant's initial WP

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes No

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes No

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes No

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes No

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes No

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes No

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes No



Date of photograph 9/22/2020

Applicant's initial MP

STATE OF NEVADA

ss.

COUNTY OF CLARK

I, MICHAEL PING, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 23rd day of September, 2020

Notary Public

K. BAYARD
Notary Public, State of Nevada
Appointment No. 16-2097-1
My Appt. Expires Apr 15, 2024

(seal)

Applicant's initial MP

ADDITIONAL INFORMATION

- N/A -

Applicant's initial

14B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR NEVADA WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and **non-transferable checks only)**

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler ☐ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: WH_____)

☐ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☒ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: FOOT CARE STORE INC d/b/a Dia-Foot

Physical Address: 4280 West Windmill Lane, Ste 111 Las Vegas, NV 89139

Mailing Address: 3281 Fairlane Farms Rd, Ste 7

City: Wellington State: FL Zip Code: 33414

Telephone: 561-791-1213 Fax: 561.721-7070

Toll Free Number: _____

E-mail: jay@dia-foot.com Website: www.dia-foot.com

Facility Manager: Sara Michelle Simonson

Professional qualifications and experience of facility manager: B.A. Biology
Regional Manager at New Balance specializing in Diabetic Shoes

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☒ Other: Podiatrists

Type of Products to be handled or wholesaled be firm:

☐ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: Diabetic Footwear

APPLICATION FOR NEVADA WHOLESALER LICENSE

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate.)

Licensed as a Manufacturer by the FDA? Yes ☐ No ☒
(If yes, provide a copy of the FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1) Jameson Noorda, DPM — 68 N Pecos Road, Suite A, Henderson, NV 89074
Name — Address
Podiatrist
Business

2) Spencer Noorda, DPM — 68. N Pecos Road, Suite A, Henderson, NV 89074
Name — Address
Podiatrist
Business

3) Southern Nevada Foot & Ankle — 3000 W. Charleston Ste 6, Las Vegas, NV. 89102
Name — Address
Podiatrist
Business

4) Wesley Lyon — P.O. Box 1344, Overton, NV 89040
Name — Address
Podiatrist
Business

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

APPLICATION FOR NEVADA WHOLESALER LICENSE

This page must be submitted for all types of ownership.

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized wholesaler may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Robert Laymon

Print Name of Authorized Person

2/24/21

Date

Board Use Only	Received:	Amount: 500 Check #019995

APPLICATION FOR NEVADA WHOLESALER LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: FLORIDA

Parent Company if any: _____

Corporation Name: FOOT CARE STORE, INC d/b/a

Mailing Address: 3281 Fairlane Farms Rd, Ste 7

City: Wellington State: FL Zip: 33414

Telephone: 561-791-1213 Fax: 561-721-7070

Contact Person: Jay Josephson

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a) Robert M. Gaynor [redacted] Windsor Ct. Boca Raton, FL
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

2) Provide the number of shares issued by the corporation. 40

3) What was the price paid per share? 1.00

4) What date did the corporation actually receive the cash assets? 1/16/96

5) Provide a copy of the corporation's stock register evidencing the above information

State of Florida
Department of State

I certify from the records of this office that FOOT CARE STORE, INC. is a corporation organized under the laws of the State of Florida, filed on January 16, 1996.

The document number of this corporation is P96000005051.

I further certify that said corporation has paid all fees due this office through December 31, 2021, that its most recent annual report/uniform business report was filed on February 5, 2021, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-third day of February, 2021

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

Secretary of State

Tracking Number: 1225251809CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

List of officers

Officer/Director Detail :

Title	VP
Name	GAYNOR, DAWN
Address	3281 FAIRLANE FARMS RD. STE 7
City-State-Zip:	WELLINGTON FL 33414

Title	S
Name	GAYNOR, DAWN L
Address	3281 FAIRLANE FARMS RD. STE 7
City-State-Zip:	WELLINGTON FL 33414

Title	PR
Name	GAYNOR, ROBERT M
Address	3281 FAIRLANE FARMS RD. STE 7
City-State-Zip:	WELLINGTON FL 33414

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Foot Care Store, Inc DBA Dia-Foot

Physical Address 4280 west Windmill Lane Suite 111

City Las Vegas State NV Zip 89139

Mailing Address (if different from physical address) 3291 Fairlane Farms Rd, Ste 1

City Wellington State FL Zip 33414

Telephone 561-798-1713 Website www.dia-foot.com

Licensing Company Email Jay @ Dia-Foot.com

Section 2: Personal Information

First Dawn Middle Lisa Last Gaynor

Alias(es, nicknames, name changes, etc.) Maiden name Schaeffer

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

Mailing Address [redacted] Windsor Court

City Boca Raton State FL Zip 33496

Telephone [redacted] Email Dawn @ Dia-Foot.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials _____

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

School Name		From - To (MM/YY – MM/YY)	
Florida Atlantic University		8/87 - 05/90	
Address	**City**	**State**	**Zip**
777 Glades Rd	Boca Raton	FL	33431
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Broward Community College		01/87 - 6/87	
Address	**City**	**State**	**Zip**
4205 Bonaventure Blvd	Weston	FL	33332
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Drake University		8/85 - 12/86	
Address	**City**	**State**	**Zip**
2507 University Ave	Des Moines	IA	50311
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Niles North High School		08/81	06/85
Address	**City**	**State**	**Zip**
9800 Lawler Ave	Skokie	IL	60077
Diploma/Degree obtained, if any			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2013 - Now	[redacted] Windsor Ct	Boca Raton	FL	33495
01/00 - 06/13	11817 Preservation Ln	Boca Raton	FL	33496

Applicant's initials _____

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

Business Name			From - To (MM/YY – MM/YY)	
Dia-Foot			01/04 - Current	
Business Address	**City**		**State**	**Zip**
3281 Fairlane Farms Rd	Wellington		FL	33414
Phone	**Title**			
561-791-1213				
Description of Duties				
Vice President, insurance billing, human Resources.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

Applicant's initials K

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-6-2021
Date

Applicant's initials

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

Dawn Gaynor
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5-6-2021
Date

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

State of FL, ss. County of Palm Beach

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

Original Signature

5-6-2021
Date

Subscribed and Sworn to before me this 6th day of May.

Notary Public Signature

JAY A. JOSEPHSON
MY COMMISSION # HH 076189
EXPIRES: April 28, 2025
Bonded Thru Notary Public Underwriters

(Seal)

Applicant's initials

APPLICATION TO BE THE DESIGNATED REPRESENTATIVE
for a Pharmacy or Wholesaler located in Nevada

Date .....

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made herein is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for Foot Care Store Inc. dba Dia-Foot
Nature of Pharmacy or Wholesaler

4280 West Windmill Lane, Ste 111 Las Vegas, NV 89139
Name and Address of Business for Which Designated Representative is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Simonson	Sara	Michelle
Last Name	First Name	Middle Name

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Southern Highlands Pkw, Apt 1145 Las Vegas, NV 89141
Present Residence Address-Street or RFD — City — State/Zip

4280 West Windmill Ln Dates Las Vegas, NV 89139
Present Business Address — Ste 111 — City — State/Zip

Operations Manager Dates April 1 → current
Present Position with the Pharmacy or Wholesaler

Phone: Residence [redacted]
Business 702.970.7166

[redacted] West Palm Beach, Palm Beach County, Florida
Date of Birth — Place of Birth (City, County, State)

36 [redacted] Female
Age — Social Security Number — Sex

Blue	Brown	White	125	Tall/Thin	5'11
Color of Eyes	Color of Hair	Complexion	Weight	Build	Height

Scars, tattoos or distinguishing marks and/or characteristics None

Are you a citizen of the United States? Yes ☑ No ☐ If alien, registration No.....

If naturalized, certificate No..... Date.....

Place..... (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single ☑ Married ☐ Separated ☐ Divorced ☐ Widowed ☐ Engaged ☐

Applicant's Initial SJ

A. Current Marriage _____
Date City, County and State

Spouse's full name (Maiden) _____ SS# or ITIN _____

Date of Birth _____ Place of Birth _____

Resident address _____
Street City State Zip

Telephone: Residence _____ Business .....

Spouse's employer _____ Occupation _____

Address of employer _____
Street City State Zip

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place	Residence Address

B. Child Support Information:

Please mark the appropriate response:

- ▬ I am not subject to a court order for the support of child.
- ▬ I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- ▬ I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial _____

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name_____

Address_____

Contact person_____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Eric O. Simonson	[redacted]	[redacted] Royal Palm Beach Blvd Royal Palm Beach, FL 33411	Landscape Nursery Supervisor/manager
Mother	Ruth E. Simonson (Bagley)	[redacted]	[redacted] Royal Palm Beach Blvd Royal Palm Beach, FL 33411	Retired - Palm Beach County Fire Rescue - Fire Inspector
Father-in-Law				
Mother-in-Law				

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Christopher M.O. Simonson	[redacted]	[redacted]-B Quiet Woods Rd. Wellington, FL 33414	Fire Sprinkler Designer
Spouse	Victoria Simonson (Lewis)	[redacted]	[redacted]-B Quiet Woods Rd. Wellington, FL 33414	Administrative Assistant to a Financial Adviser SJE Associates.
Spouse				
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School				Yes / No
High School	Wellington High School	Wellington, FL		(Yes) / No
College University	Peace College	Raleigh, NC	2002 - 2006	(Yes) / No
Other				Yes / No

Type of degree obtained, if any Bachelors - Biology

College or university where obtained Peace College, Raleigh, North Carolina

Applicant's initial _____

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes (No)

Branch_____ Date of entry-active service_____

Date of separation_____ Type of discharge_____

Rating at separation_____ Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes No If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes (No)

County_____ State_____ Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes (No) If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes (No) If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes (No)

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes (No)

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes (No)

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes (No)
If yes, when?_____ city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes (No)
If yes when?_____ city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes (No)
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial_____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes ~~No~~ (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes ~~No~~ If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
- Aug 1999	11193 66th St. N.	Royal Palm Beach	FL 33412
Aug 1999 - Aug 2002	13170 -B Quiet Woods Rd	Wellington	FL 33414
Aug 2002 - May 2006	15 E Peace Street	Raleigh	NC 27604
June 2006 - June 2007	2401 Ravenglass Cr.	Raleigh	NC 27612
June 2007 - Dec 2010	406B E Whitaker Mill Rd	Raleigh	NC 27608
Jan 2011 - June 2013	15 E Peace Street	Raleigh	NC 27604
June 2013 - Nov 2016	13170 -B Quiet Woods Rd.	Wellington	FL 33414
Dec 2016 - current	[redacted] Northwood Rd, [redacted]	W.P.B.	FL 33407
May 2019 - current	[redacted] Royal Palm Beach Blvd	R.P.B.	FL 33411

Applicant's initial Suf.

8. EMPLOYMENT:

A designated representative must document that he or she has been employed for at least 6,000 hours in pharmacies or wholesalers in a capacity related to the dispensing and distribution of and record keeping related to prescription drugs. Please provide the following information to document your hours of employment.

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
July 2020 - current	Dia-Foot 3281 Fairlane Farms Rd., St. 7 Wellington, FL 33414	currently 1,200hrs

Title	Description of Duties	Name of Supervisor
Facilities Manager - Assistant Operations Manager	- See attached for description of duties	Robert Gaynor DPM, CPed. President & CEO

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours
NOV 2013 - Oct 2019	6000 Glades Rd, Ste 1234 Boca Raton, FL 33431	New Balance +21,000 hrs.

Title	Description of Duties	Name of Supervisor
Manager - Fit Specialist	- See attached for description of duties	Kenny Sokolow, owner

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

Month and Year	Name/Mailing Address of Employer/Business	Number of Employed Hours

Title	Description of Duties	Name of Supervisor

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial _____

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Paul Weiner	Diabetic Footwear & Supply	Boca Raton	FL		[redacted]	6 yrs.
Name / owner	Home / Business					
Lauren O'Neill	Corporate Communications Specialist - Arthrex	Naples	FL		[redacted]	21 yrs.
Name / Employer	Home / Business					
Patti Kaddis	-	West Palm Beach	FL		[redacted]	8 yrs.
Name / Owner - Run and Roll	Home / Business					
Jimmie Overton		Raleigh, NC			[redacted]	15 yrs.
Name / Chief Supervisor - Retired	Home / Department for Environmental and Natural Resources					
Debbie Potter		Wilmington, Nc			[redacted]	10 yrs.
Name / Former nurse @	Home / William Peace University					

10. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
Doctor	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

Yes — (No)

If yes, state type, where and years held

.....

.....

.....

11. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes — (No)
If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

.....

.....

.....

12. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes — (No)

.....

13. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes — (No)

.....

If yes to the above, state where, when and for what reason:

.....

.....

Applicant's initial SMJ.

14. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes → (No)

15. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes → (No)

16. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes → (No)

17. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a wholesaler Yes → (No)

18. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes → (No)

19. Will you be actively involved in and aware of the daily operation of the pharmacy or wholesaler? (Yes) → No

20. Will you be employed fulltime with the pharmacy or wholesaler? (Yes) → No

21. Will you be present at the site of the pharmacy or wholesaler during its normal operating hours? (Yes) → No

A



Date of photograph 2/24/21

Applicant's initial SJ

STATE OF Florida
ss.

COUNTY OF Palm Beach

I, Sara Michelle Simonson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a wholesaler license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Wholesaler and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Wholesaler as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and its agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and its agents, as a result of my applying to be a designated representative for a pharmacy or wholesaler in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 24th day of

Notary Public

JAY A. JOSEPHSON
MY COMMISSION # HH 076189
EXPIRES: April 28, 2025
Bonded Thru Notary Public Underwriters

(seal)

Applicant's initial

ADDITIONAL INFORMATION

Applicant's initial_____

Attachment

Dia-Foot – Wellington, FL | July 2020 - current
Facility Manager - Assistant Operations Manager

Responsibilities include but not limited to the operations process of placing orders, picking, invoicing, and shipping merchandise. General oversight of all daily operations with emphasis on compliance, and enforcement of policies and procedures. Completed vendor specific Fit Specialist certifications for fitting of diabetic shoes and inserts.

Address:
3281 Fairlane Farms Road, Ste 7
Wellington, FL 33414

Supervisor:
Robert M. Gaynor DPM, C.Ped
President and CEO Dia-Foot

Hours Employed: currently 1200 hours

New Balance – Boca Raton, FL | November 2013 - October 2019
Manager - Fit Specialist

Seasoned retail professional with specialty experience managing daily operations in a fast pace environment. Executed a variety of marketing and sales promotions to drive traffic to the store and build the New Balance brand in the community. Responsible for achieving profitable sales results while monitoring and managing all expenses. Responsible for building a strong team of Fit Specialists and coaching them to provide a best-in-class guest experience. Made decisions and recommendations on hiring, training, salary administration, performance management, and development. Sales lead and Fit Specialist specializing in implementing a robust Doctor referral and corporate wellness program.

Address:
6000 Glades Road, Ste 1234
Boca Raton, FL 33431

Supervisor:
Kenny Sokolow
Owner

Hours Employed: +21,000 hours

EDUCATION

Peace College Raleigh, North Carolina | May 2006
Bachelors of Arts in Biology
Raleigh, North Carolina | May 2004
Associates of Arts

PERSONAL HISTORY RECORD for Pharmacy, MDEG & Wholesaler

2636

Date 2/24/2021

GENERAL INSTRUCTIONS

Type an answer to every question. If a question does not apply to you, so state with N/A. If space available is insufficient, continue on page 10 or use a separate sheet and precede each answer with the appropriate title. Do not misstate or omit any material fact(s) as each statement made hererin is subject to verification. Applicant must initial each page, as provided in lower right hand corner. By placing his initials on each page, the applicant is attesting to the accuracy and completeness of the information contained on that page.

All applicants are advised that this personal history record is an official document and misrepresentation or failure to reveal information requested may be deemed to be sufficient cause for the refusal or revocation of a license.

All applicants are further advised that an application for a license, finding of suitability or for other action may not be withdrawn without the permission of the licensing agency.

Application for FOOT CARE STORE, INC d/b/a Dia-Foot
Nature of License

DIA-FOOT 4280 West Windmill Lane Las Vegas, NV 89139
Name and Address of Establishment for Which License Is Requested

If applicable, Name Under Which It Is Now Operated

1. PERSONAL INFORMATION:

Gaynor (Last Name) Robert (First Name) Mark (Middle Name)

Alias(es, Nicknames, Maiden Name, Other Name Changes, Legal or Otherwise)

[redacted] Windsor Ct (Present Residence Address-Street or RFD) Boca Raton, FL (City) 33496 (State/Zip)

3281 Fairlane Farms Rd (Present Business Address) Dates Wellington, FL (City) 33414 (State/Zip) 67 years

President (Occupation) Dates 2004- Present

CEO DIA-FOOT

Phone: Residence [redacted]

[redacted] (Date of Birth) Detroit, Wayne County / MI (Place of Birth (City, County, State)) Business 561 721 7063

57 (Age) [redacted] (Social Security Number or ITIN) (Sex)

Color of Eyes	Color of Hair	Complexion	Weight	Build	Height
Hazel	Brown	Clear	180	Slim	62

Scars, tattoos or distinguishing marks and/or characteristics Ø

Are you a citizen of the United States? (Yes) No If alien, registration No

If naturalized, certificate No Date

Place (If naturalized, document must be verified.)

2. MARITAL INFORMATION:

Single Married Separated Divorced Widowed Engaged

Applicant's initial

A. Current Marriage 11/2/91 (Date) City, County and State

Spouse's full name (Maiden) Dawn Gaynor SS# or ITIN [redacted]

Date of Birth [redacted] Place of Birth Chicago, IL.

Resident address [redacted] Windsor Ct. Boca Raton, FL. 33496
Street City State Zip

Telephone: Residence [redacted] Business 561 791 1213

Spouse's employer Fast Cash Store Inc. Occupation Billing

Address of employer 3281 Fairlane Farms Rd Wellington, FL. 33414
Street City State Zip

B. **Previous Marriages**: If ever legally separated, divorced, or annulled, indicate below:

Name of Spouse	Date of Order or Decree	Date of Place of Marriage	Nature of Action	City County and State
Ø				

List of names, current address and telephone numbers of previous spouses:

Name	Street	City	State	Zip	Telephone
Ø					

3. FAMILY INFORMATION:

A. Children and Dependents:

List all children, including step-children and adopted children and give the following information:

Name	Birth Date	Birth Place			Residence Address
Zackary Gaynor		Boca Raton, FL	[redacted]	[redacted]	Marbella Circle Boca Raton, FL 33433
Mandi Gaynor		Boca Raton, FL			Windsor Ct Boca Raton, FL 33496
Alex Gaynor		Boca Raton, FL			Windsor Ct Boca Raton FL 33496

B. Child Support Information:

Please mark the appropriate response:

- [x] I am not subject to a court order for the support of child.
- [ ] I am subject to a court order for the support of one or more children and am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order; or
- [ ] I am subject to a court order for the support of one or more children and NOT in compliance with the order or a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.

Applicant's initial [redacted]

FAMILY INFORMATION-Continued

District attorney or public agency responsible for enforcing the child support order:

Name_____

Address_____

Contact person_____

C. Parents:

List names, residence addresses, dates of birth and most recent occupations of parents, step-parents, parents-in-law or legal guardian. If retired or deceased, list last address and occupation.

	Name (Maiden)	Birth Date	Address	Occupation
Father	Harold Gayman	[redacted]	[redacted] Cloud Peak Dr. Boynton Beach, FL 33473	Retired
Mother	Fermanda Gayman		Deceased	
Father-in-Law				
Mother-in-Law				

D. Brothers and Sisters:

List names, residence addresses, dates of birth and most recent occupations of brothers and sisters and of their respective spouses.

	Name (Maiden)	Birth Date	Address	Occupation
	Steve Gayman	[redacted]	[redacted] Napoli Woods	Retired
Spouse	Linda Gayman		Delray Beach, FL. 33446	Billing
	Larry Gayman		[redacted] Clarendon	Sales
Spouse	Teresa Gayman		Bloomfield Hills, MI 48302	HR
Spouse				
Spouse				

4. EDUCATION:

	Name of School	Location	Dates Attended	Graduate
Grammar School	West Maple	Birmingham, MI	73-77	Yes / No
High School	Groves HS	Birmingham, MI	77-81	Yes / No
College University	Mich. St. University Ferris State	E. Lansing MI. Big Rapids MI	81-83 83-84	Yes / No
Other	VOMHS	Des Moines, IA	84-88	Yes / No

Type of degree obtained, if any DPM, BS, AS

College or university where obtained Ferris State, VOMHS

Applicant's initial_____

5 MILITARY INFORMATION:

A. Have you ever served in any armed forces? Yes No

Branch_____Date of entry-active service_____

Date of separation_____Type of discharge_____

Rating at separation_____Serial number_____

While in the military service were you ever arrested for an offense which resulted in summary action, a trial or special or general court martial? Yes No If yes, furnish details on page 10. (List all incidents regardless of where they occurred-foreign or domestic.)

B. Have you registered for the draft? Yes No

County_____State_____Date registered_____

6. ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS: (Include those arrests in which you were not convicted.)

A. Have you ever been arrested, detained, charged, indicted or summoned to answer for any criminal offense or violation for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) Yes No If yes, give details in space provided below. List all cases without exception.

Date of Arrest	Age	Charge	Location-City and State	Deposition/Date	Arresting Agency

B. Has a criminal indictment, information or complaint ever been returned against you, but for which you were not arrested or in which you were named as an unindicted co-party? Yes No If yes. furnish details on page 10.

C. Have you ever been questioned or deposed by a city, state, federal or law enforcement agency, commission or committee? Yes No

D. Have you ever been subpoenaed to appear or testify before a federal, state or county grand jury, board or commission? Yes No

E. Have you ever been subpoenaed to testify for any civil, criminal or administrative proceeding or hearing? Yes No

F. Have you ever had a civil or criminal record expunged or sealed by a court order? Yes No
If yes, when?_____city, county and state_____

G. Have you ever received a pardon or deferred prosecution for any criminal offense? Yes No
If yes when?_____city, county and state_____

H. Has any member of your family or of your spouse's family ever been convicted of a felony? Yes No
If you answer to any of the above questions (B through H) is yes, furnish details on page 10.

Name	Relationship	Charge	Location	Date

Applicant's initial_____

ARRESTS, DETENTIONS, LITIGATIONS AND ARBITRATIONS-Continued

I. Have you, as an individual, member of a partnership, or owner, director or officer of a corporation. ever been a part to a lawsuit as either a plaintiff or defendant or an arbitration as either a claimant or respondent?
Yes → No → (Other than divorces)
If yes, give details below. List all cases without exception, including bankruptcies:

Plaintiff/Defendant or Claimant/Respondent	Date Filed	Court and Case Number	City, County and State	Disposition/Date

J. Has any general partnership, business venture, sole proprietorship or closely held corporation (while you were associated with it as an owner, officer, director or partner) been a party to a lawsuit, arbitration or bankruptcy?
Yes → No → If yes, complete the following:

Name of Entity	Type of Entity	Approximate Date(s) of Lawsuit/Arbitration/Bankruptcy

7. RESIDENCES:

List all residences you have had for the last 25 years:

Month and Year (From-To)	Street and Number	City	State or County
1993- 2000	20155 Palm Island Dr.	Boca Raton,	FL
2000- 2013	11817	Preservation LN	Boca Raton, FL
2013- Present	[redacted]	Windsor CT	Boca Raton, FL

Applicant's initial _____

8. EMPLOYMENT:

Beginning with your current employment, list your work history, all businesses with which you have been involved, and/or all periods of unemployment since 18 years of age. Also, list all corporations, partnerships or any other business ventures with which you have been associated as an officer, director, stockholder or related capacity.

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
11/89 - 2012	Foot Care Specialists	sold Practice
Title	**Description of Duties**	**Name of Supervisor**
Podiatrist	Podiatrist	

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
1/2014 - Present	DIA Foot	
Title	**Description of Duties**	**Name of Supervisor**
President	Sales / Marketing	

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

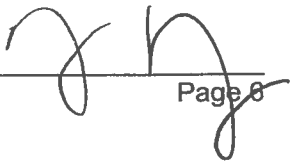
Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

Month and Year	Name/Mailing Address of Employer/Business	Reason for Leaving
Title	**Description of Duties**	**Name of Supervisor**

If additional space is needed, continue on page 10 or provide attachment.

Applicant's initial 

9. CHARACTER REFERENCES:

List five character reference who have know you five years or more. Do not include relatives, present employer or employees.

Name of Where Employed	Street	City	State	Zip	Telephone	Years Known
Name Dorey Manolakas	Home [redacted]	76 Iverson PL	Delray Bch, FL	33446	[redacted]	1993
Employer retired	Business N/A					
Name Lonny Unger	Home [redacted]	St. Annes Way	BOCA, FL	33496	[redacted]	2013
Employer retired	Business retired					
Name Norbert Gerber	Home [redacted]	Carlton PL	BOCA, FL	33496	[redacted]	1994
Employer self	Business 22191 Powerline Rd		BOCA, FL	33433	561-391-6336	
Name David Friedman	Home [redacted]	NW 53rd Cir	BOCA, FL		[redacted]	2013
Employer Glenmede	Business same as home - Virtual			33496		
Name Dan Snyder	Home [redacted]	Waverly LN	BOCA, FL		[redacted]	2016
Employer retired	Business retired					

10. Do you have any safe deposit box or other such depository, access to any depository or do you use any other person's depository? Yes ~~No~~

If yes, complete the following:

Box Number or Type of Depository	Location	City and State	Authorized Users

11. Have you ever held a privileged, occupational or professional license in any state, including but not limited to the following:

Liquor	Lawyer	Race horse/race dog owner	Securities dealer	Insurance
~~Doctor~~	Contractor	Real estate broker or salesman	Barber/Cosmetologist	Gaming
Accountant	Pilot	Sports promoter	Trainer or manager	Educator

~~Yes~~ No

If yes, state type, where and years held

FL, Podiatry 1985- Present

12. Have you ever applied for a city, county of state business, venture or industry license or held a financial interest in a licensed business or industry OUTSIDE the State of Nevada? Yes No

If yes, state type, when and where and give names and locations of the businesses in which you were involved, the names and address of all partners and the agency responsible for licensing said business, venture or industry.

DHA- Foot 3281 Fairlakes Farms Rd Wellington, FL 33414 2015- Present
Foot Care Specialists- 6316 Lantana Rd #35 Lake Worth, FL 33463- 1989- 2012

Applicant's initial _____

13. Have you ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever? Yes No

14. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? Yes No

If yes to the above, state where, when and for what reason:

15. Have you ever been refused a business or industry license or related finding of suitability or been a participant in any group which has been denied a business or industry license or related finding of suitability? Yes No

16. Have you or any person with whom you have been a participant in any group been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes No

17. Have you or any person with whom you have been a participant in any group ever been found guilty, plead guilty or entered a plea of nolo contendere to any offense, federal or state, related to prescription drugs and/or controlled substances? Yes No

18. Have you or any person with whom you have been a participant in any group ever surrendered a license, permit or certificate of registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary close of a manufacturer Yes No

19. Do you have any relatives within the fourth degree of consanguinity associated with or employed in the pharmaceutical or drug related industry? Yes No

ATT

TA



Date of photograph 2/24/21

Applicant's initial

STATE OF FL

ss.

COUNTY OF Palm Beach

I, Robert Mark Gaynor, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient case for denial or revocation of a manufacturer license; that I am voluntarily submitting this application with full knowledge that Nevada Revised Statutes 639.210 (10) provides denial or revocation of the application of any person for a certificate, license, registration or permit if the holder or applicant "Has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false of fraudulent," and further, that I have familiarized myself with the contents of Nevada Statutes on Pharmacists and Manufacturer and the Controlled Substances Act, as amended, and the Regulations of the Nevada State Board of Manufacturer as promulgated thereunder and agree, if licensed, to abide thereby,

I hereby expressly waive, release and forever discharge the State of Nevada, the licensing agency and their agents from any and all manner of action and causes of action whatsoever which I, my administrators or executors can, shall or may have against the State of Nevada, the licensing agency and their agents, as a result of my applying for a manufacturer license in the State of Nevada.

Original Signature of Applicant

Subscribed and Sworn to before me this 24th day of February

Notary Public

JAY A. JOSEPHSON
MY COMMISSION # HH 076189
EXPIRES: April 28, 2025
Bonded Thru Notary Public Underwriters

Applicant's initial

ADDITIONAL INFORMATION

Applicant's initial

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: NSI INSURANCE GROUP LLC
Agency Code: 21-220113

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Phyllis Clark
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 21BSBIP9376
Naming Foot Care Store, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 13th day of February, 2020, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

NOTARY PUBLIC STATE OF FLORIDA

Jessica Noelle Ciccone
My Commission #GG077453
Expires June 20, 2021

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of May 7, 2021.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

THE HARTFORD

RIDER

Attached to and forming part of Bond # 21BSBIP9376 ,
on behalf of Foot Care Store, Inc.
of 4280 West Windmill Lane, Ste 111, Las Vegas, NV 89139
in favor of Nevada State Board of Pharmacy
and in the amount of Twenty-Five Thousand ($25,000.00) Dollars.

It is understood and agreed that effective May 4, 2021
The Bond Limit shall be changed
from $25,000
to $100,000

All other conditions and terms remain as originally written.

Signed, Sealed, and Dated May, 7th, 2021

Hartford Fire Insurance Company

By: Phyllis A. Clark

Phyllis Clark , Attorney-in-Fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 21BSBIP9376

Application/License No. _____

Foot Care Store, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4280 West Windmill Lane, Ste 111, Las Vegas, NV 89139 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 200 Colonial Center Pkwy, 5th Fl, Lake Mary, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 26, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

21BSBIP9376

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of March, 2021.

APPLICANT/PRINCIPAL

Foot Care Store, Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Phyllis Clark, Attorney-in-fact
print name

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: NSI INSURANCE GROUP LLC
Agency Code: 21-220113

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Phyllis Clark
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 21BSBIP9376
Naming Foot Care Store, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 13th day of February, 2020, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

NOTARY PUBLIC STATE OF FLORIDA

Jessica Ciccone

Jessica Noelle Ciccone
My Commission #GG077453
Expires June 20, 2021

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of March 1, 2021.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

2651

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/02/2021

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

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

PRODUCER NSI Insurance Group LLC 5875 NW 163 Street Suite 207 Miami Lakes FL 33014	**CONTACT NAME:** Lianet Remedios **PHONE (A/C, No, Ext):** (305) 556-1488 **FAX (A/C, No):** (305) 556-3680 **E-MAIL ADDRESS:** lianetr@nsigroup.org
INSURED Foot Care Store, Inc 3281 Fairlane Farms Road Suite 4-7 Wellington FL 33414	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A:** Covington Specialty Insurance Company — 13027 **INSURER B:** Capitol Indemnity Corp — CAPIND **INSURER C:** **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 20/21 GL & XS Liab **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			VBA78432000	12/01/2020	12/01/2021	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 2,000,000 $ 100,000 $ 5,000 $ 2,000,000 $ 2,000,000 $ 2,000,000 $
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ $ $ $ $
B	[ ] UMBRELLA LIAB [X] OCCUR [X] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			XS-19023884-01	12/01/2020	12/01/2021	EACH OCCURRENCE AGGREGATE [ ]	$ 2,000,000 $ 2,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

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

RE: Property Address: 4280 West Windmill Lane, Suite 111, Las Vegas, NV 89139

CERTIFICATE HOLDER

Pacifica Blue Diamond II, LLC Pacifica Property Management, Inc.
170 Newport Center Drive
Suite 245
Newport Beach CA 92260

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Oscar Sanz

© 1988-2015 ACORD CORPORATION. All rights reserved.

Establishment:
FOOTCARE STORE INC.
Business Trade Name:
DIA-FOOT

3281 Fairlane Farms Rd Ste 7
Wellington , FL 33414
Registration Number: 3005472804
FEI Number*: 3005472804
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
FOOTCARE STORE INC.[6]
3400 FAIRLANE FARMS RD.
Wellington, FL US 33414
Owner/Operator Number: 9080027[7]

Official Correspondent:
Robert M Gaynor Dpm
3400 FAIRLANE FARMS RD.
Wellington, FL 33414
Phone: 561-7217063

15

15A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____
Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Partnership - Pages 1,2,3,7,8
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Amsino Medical, Inc.

Physical Address: 700 Enterprise Street

City: Aurora State: IL Zip Code: 60504

Telephone Number: (630) 870-3858 Fax Number: N/A

Toll Free Number: N/A

E-mail: AMI@slsny.com Website: amsino.com

Facility Manager: Torsten Nilson

Professional qualifications and experience of facility manager: Ph.D. degree, 27 years of medical device mfg. distribution experience.

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Practitioners ☒ Hospitals ☒ Wholesalers
☒ Other: Distributors, Clinics or Institutions, Distribution sites with organization.

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☒ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☒ No ☐

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: Amsino Healthcare USA, Inc.
Address: 330 Corporate Woods Parkway, Vernon Hills, IL 60061

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Richard Ya Lee
Print Name of Authorized Person

12/22/2020
Date

Board Use Only	Date Processed:_____	Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: IL

Parent Company if any: Amsino International, Inc.

Mailing Address: c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Fax: (845) 544-2481

Contact Person: Jennifer Schneider

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Amsino International, Inc. 100% Sole Shareholder 708 Corporate Center Drive, Pomona, CA 91768
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. Amsino International, Inc. 100% Sole Shareholder

3) What was the price paid per share? N/A

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: N/A

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

Amsino Medical, Inc.

Corporate Address: 700 Enterprise Street, Aurora, IL 60504 USA
FEIN: 84-3896591
amsino.com

Drug Labeler Code: 72838
Incorporation State: IL
Incorporation Date: 12/3/2019

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
NES	700 Enterprise Street Aurora, IL 60504 County: Dupage	3016248619	N/A - No CS		No	(630) 870-3858	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Torsten Nilson	700 Enterprise Street Aurora, IL 60504	President of Sales, North America	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Amsino International, Inc.	708 Corporate Center Drive Pomona, CA 91768	N/A	100%	N/A	95-4456253	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Richard Ya Lee	708 Corporate Center Drive Pomona, CA 91768	President	No	[redacted]		
Torsten Nilson	700 Enterprise Street Aurora, IL 60504	President of Sales, North America	No	[redacted]		

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

Company Packet w/ info -

FDA -

Establishment:
AMSINO MEDICAL INC.
700 Enterprise St.
Aurora , IL 60504
Registration Number: 3016248619
FEI Number*: 3016248619
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2020

Owner/Operator:
Amsino Medical Inc.
700 Enterprise St.
Aurora, IL US 60504
Owner/Operator Number: 10062127

Official Correspondent:
Torsten Nilson
700 Enterprise St.
Aurora, IL 60504
Phone: 847-7721958

FDA

FDA Home[3] Medical Devices[4] Databases[5]

✓ verified M. H 2/2/21

Establishment Registration & Device Listing

1 result found for **Establishment Registration** or
FEI Number : *3016248619*

New Search[6]

Establishment Name	▲7 ▼8	Registration Number	Current Registration Yr
AMSINO MEDICAL INC.[9]	IL/USA	3016248619	2021
• Bottle, Collection, Vacuum - Amsino Receptal Canister[10]			Repackager/Relabeler
• Apparatus, Suction, Operating-Room, Wall Vacuum Powered - Amsino Receptal[11]			Repackager/Relabeler

Can't find what you're looking for? Try a new search[12]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. ../cfrl/rl.cfm
7. ../cfrl/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=3016248619&OwnerOperatorNumber=&OwnerOper
8. ../cfrl/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=3016248619&OwnerOperatorNumber=&OwnerOper
9. ./rl.cfm?rid=236993
10. ./rl.cfm?lid=688079&lpcd=KDQ
11. ./rl.cfm?lid=688080&lpcd=GCX
12. ./rl.cfm

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. ../cfrl/rl.cfm
7. ../cfrl/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=3016248619&OwnerOperatorNumber=&OwnerOper
8. ../cfrl/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=3016248619&OwnerOperatorNumber=&OwnerOper
9. ./rl.cfm?rid=236993
10. ./rl.cfm?lid=688079&lpcd=KDQ
11. ./rl.cfm?lid=688080&lpcd=GCX

Bond -

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107318270

Application/License No. _____

AMSINO MEDICAL, INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 700 ENTERPRISE ST., AURORA, IL 60504 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CONNECTICUT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 01, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16 day of September, 2020.

AMSINO MEDICAL, INC

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

LAWRENCE F. MCMAHON, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Janice R. Martin

Witness Salvador Perez

Countersigned by:

Nevada Resident Agent James D. Castle

Certificate of Good Standing
From Formation State

2664

File Number 7258-259-4

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that

AMSINO MEDICAL, INC., A DOMESTIC CORPORATION, INCORPORATED UNDER THE LAWS OF THIS STATE ON DECEMBER 03, 2019, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS IN GOOD STANDING AS A DOMESTIC CORPORATION IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 7TH *day of* DECEMBER *A.D.* 2020 .

Authentication #: 2034202608 verifiable until 12/07/2021
Authenticate at: http://www.cyberdriveillinois.com

Jesse White

SECRETARY OF STATE

Torsten Nilson...

DRIVING GROWTH AND PROFITABILTY THROUGH
STRATEGIC INSIGHT, EXECUTION AND TEAM BUILDING

[redacted] Stone Marsh Lane • North Barrington, IL 60010 • [redacted]

C-Level Global Manufacturing and Operations Executive with an impeccable record of building and turning around operations to quickly deliver impressive top- and bottom-line results. Innovative strategist who leverages business development and engineering skills to streamline processes, generate cost savings and optimize resources. Works cross-functionally and collaboratively across all levels of the organization to motivate and inspire employees to achieve and often exceed goals. Strong sales and negotiation skills that drive win-win results with partners and customers across diverse cultures. Industry experience in medical device, healthcare, chemicals, resins and electronic housing. Provides decisive leadership at the Board and senior executive level seeking to drive growth as leader of a medical device enterprise.

Key Accomplishments:

- **Strategic Execution:** Developed and implemented medical device strategy that consolidated six operations into three, producing an annual cost savings of $180M.
- **Revenue Generation:** Built OEM business from three contracts to 35 contracts in three years and increased revenues by 48% and EBITDA margin by 7%.
- **Global Leadership:** Had multi-site P&L responsibility for $125M in revenues and 1,100 employees with facilities in the US, Mexico and China.
- **Business Transformation:** Turned around company, taking it from a loss to 8% profit margin and grew revenues 100% from $23M to $46M in 18 months, with no increase in staff, by streamlining and restructuring operations,
- **New Business Launch:** Launched injection molding business, growing annual revenues from zero to $18M in 18 months by starting a greenfield company and generating $85M in new orders

Critical Competencies for Tangible Business Outcomes

- Strategic / Tactical Planning and Execution
- Manufacturing / Operations Management
- P&L / Inventory / Cost Controls
- Facility Design / Oversight
- Sales and Marketing Management
- Project Scheduling
- Distribution Process Analysis
- M&A / Acquisition Integration
- Business Development
- Multimillion-dollar Contract Negotiations
- Strategic Partnerships and Alliances
- Vendor Management
- Conflict Resolution
- Cross-Functional Team Building and Leadership

Growth and Bottom-Line Results through Operational Excellence

Amsino Medical Inc., Aurora, IL — December 2019 – Present

Amsino Meddical Inc. is a medical device manufacturer and distributor of medical devices.

PRESIDENT of Sales, North America

Sales responsibility for North America medical device business unit.

Amsino Medical Group., Pomona, CA — 2018 – Present

Amsino Medical Group is a leading medical device manufacturer dedicated to advancing healthcare worldwide by developing, manufacturing, and marketing products that help improve the safety and effectiveness of patient care. Established in 1993 in California, USA, Amsino develops, manufactures, and markets medical products under a portfolio of recognized Amsino brands. We operate several U.S. FDA qualified manufacturing and R&D facilities in China and USA as well as sales and marketing operations in California, USA with a total headcount of approximately 1,500

PRESIDENT of Sales, North America

P&L responsibility for North America medical device and pharma business unit.

- Acqusition and Intergration of Smiths Medical Pharmaceutical facility in Vernon Hills, IL.
- Contract Manufacturer of private label sterile water, saline, and drug products.
- Offering Waste Fluid Management, Infusion Theraphy, Enteral Feeding, Respiratory and Urological devices.
- Large network of top US distributors.

Douglas Medical Products, Inc.., Mundelein, IL 2018

Contract manufacturer of private label medical devices. As a full-service contract manufacturer DMP provide customers with design, engineering, tooling, testing, regulatory support, UDI implementation and complete cost-efficient finished sterile medical devices.

PRESIDENT

P&L responsibility for medical device business. Douglas Medical Products, Inc. is an FDA registered company. DMP is a full-service contract manufacturer and a specification developer, with a broad range of 510(k)'s on file and continue to expand its offering with innovate technology. Special focus on Infusion Therapy and PVC-Free Products.

- Extensive line of IV Administration Sets, Extension Sets and TUBETECH® IV Administration Sets for peristaltic pumps.
- Enteral Feeding (ENFit) product line offering including syringes.
- Comprehensive line of Meliflex™ TPO PVC-Free compounds.
- Broad line of flexible, clear and sterile EcoFLX™ Empty IV Mixing Containers in PVC-Free and EVA materials.
- Turnkey Medical Tooling manufacturing where we manage and control the manufacturing from design to validation as per customer specification.

PrimeGuard Medical, LLC., Mundelein, IL 2016 – 2018

Leading manufacturer of high quality patented securement devices.

CHIEF EXCECUTIVE OFFICER

PrimeGuard Medical, LLC is an infection control company focusing on catheter securements. Catheter related bloodstreams infections (CRBSI) associated with peripheral catheters have an associated cost of $2 billion/year.

- Develop and execute medical device growth strategy establish sales channels through strategic alliances with OEM and Distributors.
- PrimeGuard Medical are developing additional products using this innovative technology for vein access, respiratory therapy, dialysis, wound care and patient transport.

PrimeGuard Medical is dedicated to developing solutions to enhance safety, reduce transmission of infections, repurpose caregiver's time and reduce overall hospital costs.

Tekni-Plex International, Inc., Wayne, PA 2013 – 2016

Leading manufacturers of high quality packaging and tubing materials with manufacturing sites in North America, Europe and Asia.

VICE PRESIDENT, BUSINESS DEVELOPMENT – MEDICAL

Recruited by CEO to develop and execute medical device growth strategy and integrate with the healthcare division. Charged with driving growth in the medical and healthcare sector by expanding into new business sector. Oversees mergers and acquisitions for the medical business unit from evaluation through final negotiation.

- Established new business medical business unit focus on expansion through acquisition as well as building new plants focused on assembly.
- Supported $5M facility expansion into Costa Rica based on identifying and sourcing new clients.
- Detailed business case for expanding China operations with contract manufacturing resulting in design of new building for medical device manufacturing.

Amsino International, Pomona, CA 2008 – 2012

$100M medical device manufacturer.

PRESIDENT, CONTRACT MANUFACTURING

Recruited by CEO to drive growth of OEM business. Held P&L responsibility for OEM medical device business, oversaw three manufacturing sites in China and 1100 employees and managed customers in North America and Europe.

- Grew revenues 48% from $26M to $38M. Established and implemented use of manufacturing metrics to track plant performance and quality.
- Increased profit margin by 7% by expanding customer base to include Fortune 500 companies including Abbott, Baxter, Hospira, Coloplast, CareFusion, Medline, and CR Bard.
- Negotiated long-term contracts with existing customers that generated an additional $38M in long-term revenue.

Hospira, Inc., Lake Forest, IL 2005 – 2008

$4B generic pharma and medical device manufacturer; former division of Abbott.

DIRECTOR DEVICE OPERATIONS STRATEGY
GENERAL MANAGER MOLDING OPERATIONS
Hospira, Inc. Ashland, OH and Buffalo, NY

Joined company to run the P&L of two plants with revenues of $125M+. Developed and implemented medical device strategies for the company.

- Consolidated six operations into three resulting in $180M annual savings.
- Identified non-core businesses of $76M and outsourced to international and US companies.
- Benchmarked Asian medical contract manufacturing and moved two businesses to China of $10M in revenue from US and $3M revenue from Ireland saving $2.5M in costs.
- Developed chemotherapy infusion sets for European market that generated $5M in annual revenues.
- Managed $10M sales operations for clients that included CVS, Walgreen, Rite Aid, and other retail pharmacies.

Sanmina, San Jose, CA 2002 – 2004

$10B contract provider end-to-end design, manufacturing and logistics solutions to OEM in technology medical, defense, automotive and other industrial sectors.

VICE PRESIDENT
Hired to lead multi-site operations in for three distinct US and Mexican companies with $90M+ in revenues and 1100 employees. Turned operations around to establish company's three most profitable plants.

- Created worldwide sourcing of plastic and die-casting strategy for Sanmina.
- Restructured management team and revitalized culture in two operations and created an environment of excellence and quality production that maximized profit margins.
- Generated an additional $30M in revenue by building a new plant for Carrier designed to produce its sheet metal enclosures.

Nolato Shieldmate, Inc., Itasca, IL 2000 – 2002

Acquired in 2000 by Nolato; manufacturer of cell phones for major companies including Motorola and Denso.

PRESIDENT
Hired by the CEO to turn around the newly acquired company. Reorganized operations, including assembly and plastic injection molding with 880 employees.

- Successfully turned around company to generate 8% profit margin.
- Restructured company and streamlined assembly processes.
- Doubled the revenue to $46M in 18 months without increasing headcount.

Nolato Texas, Inc., Fort Worth, TX 1998 – 2000

Division of $500M Swedish corporation which develop and manufactures polymer material products including plastic, silicone and TPE for leading customers within medical technology, pharmaceuticals, telecom, automotive, and other selected industrial sectors.

PRESIDENT
Recruited by the CEO to start a new plant in Texas. Built a greenfield operation to supply electronic housing to Nokia and Ericsson and started production in five months. Sold to and retained anchor clients Ericsson and Nokia.

- Grew revenues from zero to $18M in first 18 months while expanding the plant.

- Developed networks with vendors and contractors to systematically grow sales volume.
- Secured an $85M order from one of the major mobile phone manufacturers.

Perstorp Compounds, Inc., Florence, MA 1993 – 1998
Division of $2B Swedish chemical corporation that manufactures compounds for compression molding.

PRESIDENT
Assigned to head US subsidiary with $13M in revenues and an operating loss. Replaced management, lowered operation and utility costs increased output and productivity, optimized pricing and reduced scrap levels.

- Successfully turned around the company to generate 8% profit margin, within three years.
- Developed a new business line of plastic blast media reducing scrap by 80% and generating new revenue of $2M within 18 months.

Early Career Experience

Perstorp Polyols, Perstorp Formox, Sweden, Marketing Manager, 1991 – 1993; Chief Engineer, 1985 – 1991

Education

MS, Chemical Engineering, Lund's Institute of Technology, Sweden
BS, Physical Sciences, Lund's College, Sweden

Illinois Department of Financial and Professional Regulation

Division of Professional Regulation

JB Pritzker
Governor

Deborah Hagan
Secretary

Cecilia Abundis
Director
Division of
Professional
Regulation

CERTIFICATION OF LICENSURE

700 N. Enterprise St
Aurora, IL 60504

Licensee: License	AMSINO MEDICAL INC
Number:	203.002505
Profession:	HOME MEDICAL EQUIPMENT AND SERVICES PROVID
Date of Issuance:	01/13/2020
Expiration Date:	03/31/2024
License Status:	ACTIVE
License Method:	NON-EXAM
Disciplinary History:	Has not been disciplined

This document is a certified copy of the records maintained and kept by this department in the regular course of business as of 01/15/2021

Cecilia Abundis
Director
Division of Professional Regulation

01/15/2021
Date

Refer to the Department's Web Site at www.idfpr.com to verify professional licenses via License Look-Up.

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
AMSINO MEDICAL INC	Aurora, IL 60504	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
203002505	HOME MEDICAL EQUIPMENT AND SERVICES PROVIDER	ACTIVE	01/13/2020	01/13/2020	03/31/2021	N

Generated on: 8/26/2020 7:44:16 AM

Richard Lee Discipline Explanation

1. Arrested on 05/22/2012 in San Bernardino County, California, on suspicion of DUI-Alcohol 0.08 percent. Detention only, no charges filed due to lack of sufficient evidence

2. Arrested on 02/12/2018 in Los Angeles County, California on DUI Alcohol 0.08 percent. Convicted as Misdemeanor. Fines paid and community service completed.

SUPERIOR COURT OF CALIFORNIA, LOS ANGELES COUNTY
EAST DISTRICT, POMONA
SENTENCING MEMORANDUM

RICHARD LEE, CASE NO.: 8PC01703 -1

As to count(s): 2 Sentencing Date: 2/4/2019

☑ This is an agreed upon sentence/disposition
☑ Imposition of sentence is suspended.
☑ Defendant is placed on Summary probation for a period of 3 years 0 months on the following terms and conditions:
☑ **Defendant has credit for 1 day(s) in jail plus 0 GTWT for a total of 1 day(s). Applied to jail, work and fines as indicated below:**

WORK:

☑ **Community Labor: 10 days with credit for 1 days.** Must be completed by: 8/5/2019 Only thru court/probation approved volunteer center.
☑ All proof of completion of work must be filed in the Clerk's Office on or before the due date.
☑ Work must be completed with/at Tree Farm

FINES AND FEES: Defendant to pay fines and fees as follows:

Imposed	Credit*	Total	* Credit is based on additional jail credit of 1 day(s), or fines/fees not imposed by court (waived/not applicable).
☑ $2,047	$0.00	2,047.00	**TOTAL FINES & FEES**

OR if you were offered, and you elect to complete a fine alternative, please complete the following by the due date:

☑ 3 Days of community labor in lieu of fine. This is in addition to any work imposed for offense.
☑ $418 Total due if fine alternative completed:
$268 Fees (The fees are imposed, but are not a condition of probation)
$150 Restitution Fine/Penalties, identified by RFP* below

☑ **All fines/fees and/or the alternative must be filed/paid in the Clerk's Office on or before:** 8/5/2019

Below is a detailed breakdown of the fines/fees imposed

Imposed	w/Credit							Fee?
$390	$390	Base Fine	$0	$0	$0	$0	BASE	Fine
$390		PA, State per PC1464					P.A. ON FINES	PA
$273		PA, County per GC 76000					P.A. ON FINES	PA
$195		PA, Court Construction per GC70372					P.A. ON FINES	PA
$78		PA, Emergency Medical Services per GC 76000.5					P.A. ON FINES	PA
$39		PA, DNA Testing per GC 76104.6					P.A. ON FINES	PA
$156		PA, DNA ID per GC 76104.7					P.A. ON FINES	PA
$1,131		TOTAL OF PENALTY ASSESSMENTS		Total w/o DNA =	$936			
$78		Criminal Surcharge per PC 1465.7					CRIMSUR	PA
$150		Restitution Fine per PC 1202.4					RESTPROB	RFP *
$40		Court Operations Assessment per PC 1465.8					SECFEE	Fee
$30		Criminal Conviction per GC 70373					ICNAMIS	Fee
$10		Citation Processing per PC 1463.07, GC 29550(f)					CITEPROC	Fee
$30		Installment and Accounts Receivable per PC 1205(e) (imposed only if fine, and is collected)					INSTFEE	Fee
$1		Night Court Assessment per VC 42006 (imposed only if fine)					NC/TSGEN	Fee
$4		County Emergency Medical Air Transportation per GC 76000.10					MEDAIR	FeP
$50		Alcohol Abuse Education and Prevention per VC 23645					ALCOHED	FeP
$100		Alcohol and Drug Program per VC 23649 (imposed only if fine)					PBHEALTH	Fee
$33		Lab Services Fee per PC 1463.14					LABFUND	FeP

☑ (107) Defendant is ordered to pay a probation revocation restitution fine pursuant to penal code section 1202.44, in the same amount as the restitution fine. This fine shall become effective upon the revocation of probation.

EDUCATION:

☑ Enroll within 21 days (or within 21 days from your release from custody) and successfully complete an approved alcohol education program:
☑ (327) 3 month (AB541) The DMV will not restore your driving privilege until you successfully complete a licensed alcohol education program.
☑ (336) Defendant shall report to the Public Health Investigator to enroll in the alcohol education program. Located at:
Pomona Courthouse, 400 Civic Center Plaza, Room 537, Pomona CA 91766
☑ (471) Enroll and complete the Hospital and Morgue ("HAM") program. Must be completed by: 8/5/2019
☑ (472) Enroll and complete the Victim Impact Program put on by the Mother's Against Drunk Driving. Must be completed by: 8/5/2019
☑ All proof of completion of education must be filed in Court with a progress report on the next court date.
(This does not apply to the alcohol education program if referred to the Public Health Investigator).

ADDITIONAL PROBATION CONDITIONS:

☑ Defendant's BAC level stipulated to be: 0.09
☑ (711) Do not drive any vehicle with any measurable amount of alcohol or drugs in your blood or refuse to take and complete any blood alcohol or drug chemical test, any field sobriety test, and any preliminary alcohol screening test, when requested by any peace officer.
☑ (374) Do not drive a motor vehicle without a valid driver's license in your possession, or without liability insurance in at least the minimum amounts required by law.
☑ (710) The defendant was advised and understood that being under the influence of alcohol or drugs, or both, impairs his/her ability to safely operate a motor vehicle, and it is extremely dangerous to human life to drive while under the influence of alcohol or drugs, or both. defendant was further advised that if he/she continues to drive while under the influence of alcohol or drugs, or both, and as a result of his/her driving, someone is killed, the defendant can be charged with murder.

970A allowed on 4-4-19

☑ (975) If ordered by DMV to install an ignition interlock device must comply with their order as a condition of probation.
☑ The next hearing in this case 4-4-19 will be in Department E., not in dept S
☑ (541) Obey all laws and orders of the court.
☑ (810) Defendant acknowledges to the court that the defendant understands and accepts all the probation conditions, and defendant agrees to abide by same.
☑ (894) Upon completion of your probation/sentence you have may be eligible for a petition for dismissal pursuant to Penal Code § 1203.4, or a certificate of rehabilitation and pardon pursuant to Penal Code § 4852.01.

☑ **DEFENDANT IS ORDERED TO APPEAR ON THE NEXT COURT DATE (683):** 4/4/2019 **DEPT.: , S COURTHOUSE**

☑ Matter is set for: [ ] Proof of Enrollment [ ] Progress Report [ ] Proof of Completion [X] RESTITUTION SETTING HEARING

The court date is for the defendant to provide a progress report or proof of completion of the conditions listed above. The defendant is ordered to bring his/her own copies even if advised by program they have mailed a separate copy.

I understand, accept and will comply with the foregoing sentence and compliance dates and will return to Court as ordered.		I join and I understand that if appearing 977a that I have been ordered by the Court to provide a copy of this form to my client.
Defendant's Signature		Attorney's Signature
Defendant's Address		

PAID IN FULL

15B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Wholesaler or ☑ Ownership Change (Provide current license number if making changes: WH 01982

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7,8
☑ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,9

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Crown Laboratories, Inc.

Physical Address: 349 Lafe Cox Dr.

City: Johnson City State: TN Zip Code: 37604

Telephone Number: 423-926-4413 Fax Number: 423-926-0165

Toll Free Number: 423-926-4413

E-mail: mfogartie@crownlaboratories.com Website: www.crownlaboratories.com

Facility Manager: Seth McKee

Professional qualifications and experience of facility manager: 11 years of experience

Types of licensed outlets or authorized persons firm will serve:

☑ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers
☑ Other: Retail

Type of Products to be handled or wholesaled by firm:

☑ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☑ Other: OTC Pharmaceuticals
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☑ No ☐
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? Yes ☑ No ☐
(If yes, provide a copy of your FDA registration)

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: AmerisourceBergen Drug Corporation
Address: 3400 Fraser St Aurora, CO 80011

Name: McKesson Drug Company
Address: 1765 Fremont Drive, Salt Lake City, UT 84104

Name: Cardinal Health
Address: 6640 Echo Ave #J Reno, NV 89506

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☑ No ☐

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Seth McKee
Print Name of Authorized Person

09/28/2020
Date

Board Use Only	Date Processed:_____	Amount: _____

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Crown Laboratories Holdings Inc.

Mailing Address: 251 Little Falls Dr.

City: Wilmington State: DE Zip: 19808

Telephone: 646-362-5965 Fax: 423-630-0398

Contact Person: Jeff Bedard

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) See attached
Name Business Address

b) _____
Name Business Address

c) _____
Name Business Address

d) _____
Name Business Address

2) Provide the number of shares issued by the corporation. Unknown

3) What was the price paid per share? Unknown

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://tn.gov/health

Tennessee Board of Pharmacy
Manufacturer/Wholesaler/Distributor
1-800-778-4123

August 14, 2020

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Wholesaler/Distributor
NAME:	CROWN LABORATORIES, INC.
ADDRESS:	349 Lafe Cox Drive, Johnson City TN 37604
LICENSE NUMBER:	6054
ISSUE DATE:	May 08, 2020
EXPIRATION DATE:	May 31, 2022
CURRENT STATUS:	Licensed
STATUS DATE:	May 08, 2020
SPECIAL ENDORSEMENT:	



COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Keshia Evans

Tennessee Board of Pharmacy

VERFFACLTY

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
http://tn.gov/health

Tennessee Board of Pharmacy
Manufacturer/Wholesaler/Distributor
1-800-778-4123

August 14, 2020

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Manufacturer
NAME:	CROWN LABORATORIES, INC.
ADDRESS:	349 LAFE COX DR, Johnson City TN 37604
LICENSE NUMBER:	82
ISSUE DATE:	August 05, 2005
EXPIRATION DATE:	April 30, 2022
CURRENT STATUS:	Licensed
STATUS DATE:	August 05, 2005
SPECIAL ENDORSEMENT:	

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Keshia Evans

Tennessee Board of Pharmacy

VERFFACLTY

State of Tennessee
Department of Health

12110156
28097

TENNESSEE BOARD OF PHARMACY
WHOLESALE/DISTRIBUTOR
CROWN LABORATORIES, INC.
349 LAFE COX DRIVE
JOHNSON CITY TN 37604

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006054
EXPIRATION DATE: 05/31/2022

John W Tidwell
DIRECTOR, HEALTH RELATED BOARDS

COMMISSIONER

DCF171

NEVADA STATE BOARD OF PHARMACY

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

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: See attached letters

Address: _____

City: _____ State: _____ Zip: _____

I hereby authorize the _____ to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant _____

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☐ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☐ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☐ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☐ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☐ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal

State of Tennessee
Department of Health

12110155
28098

TENNESSEE BOARD OF PHARMACY
MANUFACTURER
CROWN LABORATORIES, INC.
349 LAFE COX DR
JOHNSON CITY TN 37604

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000000082
EXPIRATION DATE: 04/30/2022

John W Sidwell
DIRECTOR, HEALTH RELATED BOARDS

COMMISSIONER

DCF171

Drug Establishments Current Registration Site

Á SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

ý TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

è EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **crown laboratories**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Crown Laboratories	1019820	079035945	MANUFACTURE;	349 Lafe Cox Drive, Johnson City, Tennessee (TN) 37604, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Tuesday, Oct 22, 2019

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Verified
MS
11/12/20

2686

The National Association of Boards of Pharmacy®

hereby awards

Verified-Accredited Wholesale Distributors®

Accreditation

to

Crown Laboratories, Inc

located at

349 Lafe Cox Dr, Johnson City, TN 37604

This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.

Carmen A. Catizone, Executive Director/Secretary

October 29, 2017 - October 28, 2020

Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | www.nabp.pharmacy

Reaccreditation Process

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
Crown Laboratories, Inc	349 Lafe Cox Dr Johnson City, TN 37604	Reaccreditation in process

Seth McKee

[redacted]Ridgemont Street
Bristol, TN 37620
[redacted]

Professional Experience:

Current position: General Manager Crown Laboratories.

- Oversight of over 20 million in capital projects. Leads FDA and client audits of the facility.
- Administers projects from conceptual review, capital request, design, and build, to commissioning and turnover.
- Directs manufacturing, packaging and technical personnel for production of drugs and devices. Assures that production and preventative maintenance schedules are kept.
- Facilitates weekly meetings with all departments, including executive staff, to sustain communications regarding plant issues, ongoing projects, and environmental health and safety concerns.
- 15 years of experience in a pharmaceutical environment troubleshooting, repairing, and maintaining manufacturing, packaging equipment. Strong knowledge of HVAC systems, high-pressure steam systems and USP water systems.

Education /Other:

MBA (Specialization in Finance)
King College, Bristol TN

Bachelor Degree, Business Administration (Magna cum Laude)
King College, Bristol TN

2 year Technical Degree, HVAC
Virginia Highlands Community College, Abingdon, VA

Lean & Six Sigma Green Belt

Licensed TN mechanical contractor

40under40 Honoree Tri Cities Business Journal

2012 Lead Bristol Graduate

Work Experience:

Director of Manufacturing — **Upm Pharmaceuticals Bristol, TN 37620**
May 2014 -2016

Facilities Manager — **Upm Pharmaceuticals/ Pfizer**
March 2011-May 2014

Maintenance Supervisor — **King Pharmaceuticals, Bristol, TN 37620**
June 2009 – March 2011

- Led team of 9 performing preventive maintenance, repair, and calibrations.
- Monitored upkeep of all production equipment, 11 buildings, and all utilities.
- Created, reviewed, and approved departmental SOPs and maintenance procedures.
- Managed department expense and assigned capital projects' budgets.
- Led planning/execution of plant maintenance annual shutdown activities.
- Improved operational efficiencies: on-call program, maintenance systems.
- Investigated Notice of Events and implemented corrective/preventive action plans.
- Coordinated Arc Flash study/education program for the facility.
- Facilitated compliance of team's activities and facility with FDA, OSHA, and EPA.
- Maintained the Building Automation System for environmental monitoring/control.
- Provided professional development opportunities to team members.
- Tracked/monitored departmental key performance indicators.
- Supplemented internal resources with contractors/vendors as required.
- Provided support for capital projects managed by Corporate Engineering.
- Promoted safe workplace: education, Lock Out Tag Out program, PPE programs.
- Resolved quality, safety, and insurance audit findings related to facility maintenance.

Maintenance Technician **King Pharmaceuticals, Bristol, TN 37620**
May 2002 – June 2009

- Performed skilled maintenance activities to support all facility operations.
- Diagnosed and repaired HVAC equipment, production/packaging and utility equipment, electrical and system utility problems, and assisted with installation of new equipment.
- Responded to call-ins and maintenance emergencies as needed.
- Worked with outside consultants to troubleshoot and repair complex production equipment.
- Worked closely with all departments to ensure that maintenance needs were addressed promptly.
- Communicated regularly with supervisor to alert him to any issues related to the operation of the facility.

HVAC Service Technician **Comfort Systems, USA Bristol, VA 24201**
1998 – 2002

- Repaired several different types of HVAC equipment.
- Responded to after-hour service calls.
- Worked a rotating 24-7 on-call week.
- Operated away from the home office for days and weeks at a time.
- Solely responsible for the maintenance of all CVS pharmacies in Knoxville, Chattanooga, and Tricities areas this work included Rooftop units, coolers, freezers etc.

- ServiceNow

- ServiceNow

CROWN
SKIN SCIENCE FOR LIFE

Crown Ownership

Crown Laboratories Holdings, Inc.
251 Little Falls Drive
Wilmington, Delaware 19808

Majority Owners in Crown Laboratories Holdings, Inc.

Hildred Holdings LLC, Series I
745 Fifth Ave., Suite 1702
New York, NY 10151
(646) 362-5968

42.4% of ownership

Greenspring Opportunities V, L.P.
100 Painters Mill Rd., Suite 700
Ownings Mill, MD 21117
(410) 504-6441

13.2% of ownership

Montreux Growth Partners II, L.P.
Four Embarcadero Center, Suite 3720
San Francisco, CA 94111
(650) 234-1200

12.5% of ownership

CROWN
SKIN SCIENCE FOR LIFE

Crown Structure Chart



349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

CROWN
SKIN SCIENCE FOR LIFE

Board of Directors

David Solomon
Chairman of the Board and Partner at Hildred Capital Partners, LLC

Jeff Bedard
President/CEO of Crown Laboratories, Inc.

Andrew Goldman
Managing Director and Chief Investment Officer with Hildred Capital Partners, LLC

Stephen Hallenbeck
Principal and the Director of Private Equity with Hildred Capital Partners, LLC

Jack Songster
Chief Operations Officer of Crown Laboratories, Inc.

Dan Turner
Managing Director, Montreux Equity Partners

Alyson Hogg
Founder Vita Liberata

Joe Proctor
President of Crown Aesthetics

Adair Newhall
Principal, Greenspring Associates

Wael Fayad
Managing Director, Hildred Capital Management

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

CROWN
SKIN SCIENCE FOR LIFE

Corporate Officers

President/CEO – Jeff Bedard
[redacted] Rangewood Road
Piney Flats, TN 37686

Chief Operations Officer – Jack Songster
[redacted] Whispering Lake Drive
Jonesborough, TN 37659

Chief Science Officer – Thomas Hitchcock
[redacted] Valley Ridge Road
Dallas, TX 75220

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CROWN LABORATORIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CROWN LABORATORIES, INC." WAS INCORPORATED ON THE NINTH DAY OF JANUARY, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6651915 8300

SR# 20207269792

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203670103

Date: 09-16-20

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 12BSBIL4789

Application/License No. _____

Crown Laboratories, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
207 Mockingbird Lane, Johnson City, TN 37604, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Connecticut
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 09/28/2020.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of September, 2020.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Courtney Gomez
Surety Company's Representative

Courtney Gomez, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 *or fax:* 860-757-5835

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: THE B&G GROUP INC
Agency Code: 12-122343

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Courtney Gomez
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 12BSBIL4789
Naming Crown Laboratories, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 13th day of February, 2020, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

NOTARY PUBLIC STATE OF FLORIDA

Jessica Noelle Ciccone
My Commission #FF029702
Expires June 20, 2021

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of September 28, 2020.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

CROWN
SKIN SCIENCE FOR LIFE

Alabama Disciplinary Action

On July 15, 2019, the Alabama Board of Pharmacy fully executed a Consent Order (referred to as the "Consent Order") to resolve *In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. 192569*, Case No. 18-L-0111 before the Alabama Board of Pharmacy. In the Consent Order, "[c]ounsel for the parties stipulate that Crown denies for all legal purposes other than this proceeding the allegations set forth in the Statement but further stipulate the Board would introduce sufficient evidence to prove Crown (a) entered into the Consent Decree of Permanent Injunction filed in the United States District Court, E.D. Tenn., 2: l 7-cv-36, dated July 26, 2017, and attached to the Statement (the 'Consent Decree'), (b) is required to comply with the Consent Decree in that federal action, and (c) is required to comply with the Consent Decree as part of this Consent Order in this action."

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
CROWN LABORATORIES, INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer Permit No. 192569	)	**CASE NO: 18-L-0111**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Crown Laboratories, Inc.
349 Lafe Cox Drive
Johnson City, Tennessee 37604

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 11e, 2019 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Crown Laboratories, Inc. (Crown) as a Manufacturer should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted based upon any or all of the following:

COUNT ONE

The Complaint for Permanent Injunction and/or the Consent Decree of Permanent Injunction attached hereto cumulatively as Exhibit "A" in a case styled United States of America v. Crown Laboratories, Inc. et al. in the United States District Court for the Eastern District of Tennessee, Civil Action 2:17-cv-36.

The Board alleges that each complained of act in deviation of 21 USC 331(a), (d) or (k) as alleged in the Complaint or Consent Decree is a separate and distinct violation.

CROWN
SKIN SCIENCE FOR LIFE

New Hampshire Administrative Disciplinary Action

At its April 15, 2020 Meeting, the New Hampshire Board of Pharmacy ("Board") reviewed the change of ownership application submitted by Crown Laboratories, Inc. on March 31, 2020. While reviewing the application, the Board noted that the application included documentation of disciplinary action in Alabama and Arizona from 2019 and 2020. This discipline had not been previously reported to the New Hampshire Board of Pharmacy. Per RSA 318:51-a, V and Ph I 002.12, the Board must be notified within 30-days of any changes, including disciplinary action in other states. Accordingly, the Board sees fit to assess an administrative fine of $150.00. This fine shall be a non-disciplinary, administrative fine.

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 14th day of January, 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. CROWN LABORATORIES, INC., a corporation and JEFFERY BEDARD, an individual, Defendants.	Civil Action No.: _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Crown Laboratories, Inc. ("Crown" or "the firm") is a corporation incorporated and registered to do business in Tennessee. Crown operates at its principal place of business and drug manufacturing facility, which is located at 349 Lafe Cox Drive, Johnson City, Tennessee (the "Facility"), within the jurisdiction of this Court.

5. Crown manufactures, processes, packs, labels, holds, and distributes a variety of prescription and over-the-counter ("OTC") drugs including, but not limited to, prescription urea cream and lotion, and prescription Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), which are the subject of this action. Specifically, Crown manufactures, processes, packs, labels, holds, and distributes in interstate commerce Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) under its own labels. Crown also manufactures, processes, packs, labels, holds, and distributes in interstate commerce Sodium Sulfacetamide as a contract manufacturer for another pharmaceutical firm.

6. Defendant Jeffery Bedard is Crown's Chief Executive Officer. He is responsible for, and has authority over, all operations at the firm. He has the authority and duty to prevent, detect, and correct objectionable conditions. He performs his duties at the Facility, within the jurisdiction of this Court.

DEFENDANTS' VIOLATIONS OF THE ACT

Unapproved New Drugs

7. A product is a drug within the meaning of the Act, inter alia, if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

8. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

9. The products Defendants introduce or deliver for introduction into interstate commerce are drugs within the meaning of the Act because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and/or intended to affect the structure or any function of the body of man. Specifically, according to the products' labels, Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, and Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) are intended to treat hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratosis, and calluses, and Sodium Sulfacetamide is intended to treat acne vulgaris, acne rosacea, and seborrheic dermatitis.

10. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or any drug . . . the

composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions." 21 U.S.C. § 321(p).

11. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j). It is a violation of the Act to introduce or deliver, or cause to be introduced or delivered, into interstate commerce a new drug that is neither approved nor exempt from approval. 21 U.S.C. § 331(d).

12. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are "new drugs" within the meaning of the Act, inter alia, because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. 21 U.S.C. § 321(p)(1).

13. There is no application under 21 U.S.C. § 355 on file with FDA for Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), or Sodium Sulfacetamide that would allow Crown to introduce or deliver these products, or cause them to be introduced or delivered, into interstate commerce to the public.

14. Defendants' introduction or delivery for introduction of these drug products into interstate commerce therefore violates 21 U.S.C. § 331(d).

Misbranded Drugs

15. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

16. A drug is misbranded if its labeling fails to bear "adequate directions for use," and does not fall within a regulatory exemption from this requirement. 21 U.S.C. § 352(f)(1); 21 C.F.R. Part 201, Subpart D.

17. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(B). The labeling of these products state that they are intended for "Rx Only" use.

18. Defendants' Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide are misbranded because they do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.100 or 201.115. A new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its approved application. See 21 C.F.R. § 201.115. Moreover, a prescription drug that is a new drug can qualify for the exemption from the adequate directions for use requirement if its labeling bears the information authorized by an approved new drug application. See 21 C.F.R. § 201.100(c)(2). New drugs that lack an approved NDA, such as Defendants' prescription drugs, cannot qualify for either of these exemptions and therefore are misbranded as a matter of law.

19. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

20. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug, as defined by 21 U.S.C. § 321(g)(1), to become misbranded, within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Interstate Commerce

21. During the most recent inspection of the Facility between February 22 and 25, 2016, FDA documented Defendants' shipment of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion to Georgia and Utah, and of Dermasorb XM Trade Kit (Urea 39% Cream and Moisturizer) to California. FDA also documented Defendants' shipment of Sodium Sulfacetamide to Ohio. These shipments constitute the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. §§ 331(a) and (d).

22. Defendants receive raw materials from outside of Tennessee, which they use to manufacture their drug products. For example, Defendants receive the active pharmaceutical ingredients Urea USP from Ohio and Sodium Sulfacetamide Monohydrate from Mississippi. Therefore, the interstate commerce element under 21 U.S.C. § 331(k) is met.

HISTORY

23. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

24. During a meeting with Defendants on December 2, 2015, FDA notified

Defendants that unapproved, marketed drugs are not listed in the FDA Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, (35th ed. 2015), which is a compilation of drugs approved by FDA on the basis of safety and effectiveness whose applications have not been withdrawn or suspended for safety or effectiveness reasons and FDA's evaluations on the therapeutic equivalence of drugs, and that the marketing of these products absent an approved application may violate the Act and subject them compliance action.

25. During an inspection of the Facility between March 2 and 3, 2015, FDA documented Defendants' distribution in interstate commerce of Rea Lo (40% Urea) Cream and Rea Lo (40% Urea) Lotion. By letter dated May 13, 2015, FDA explained to then counsel for Defendant Crown that 40% Urea Cream, 40% Urea Lotion, 39% Urea Lotion, and Sodium Sulfacetamide are new drugs that are subject to the Act's premarket approval requirement.

26. During an inspection of the Facility between February 10 and 14, 2014, FDA documented, among other things, Defendants' manufacturing and distribution in interstate commerce of prescription urea drugs privately labeled for Ascend Laboratories, LLC (hereafter, "Ascend"), specifically products labeled as Ascend Urea Cream 40% and Ascend Urea 40% Lotion. FDA also documented Defendants' manufacturing and distribution in interstate commerce of Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer) and Sodium Sulfacetamide during the inspection. The FDA investigator discussed the potential unapproved status of these drugs with firm management, including Defendant Bedard, and made them aware of FDA's Compliance Policy Guide Section 440.100, Marketed New Drugs Without Approved NDAs or ANDAs, amended September 19, 2011 ("CPG Section 440.100"); see also 76 Fed. Reg. 58398-01 (Sept. 21, 2011). In CPG Section 440.100, FDA notified manufacturers and

COPY OF THE FOREGOING MAILED
this 2nd day of March, 2020 to:

Jeanne M. Galvin
Seth T. Hargraves
Assistant Attorney General
2005 North Central Ave., SGD/LES
Phoenix, Arizona 85004
Attorneys for the State

Doc#8519750

distributors that any product that is being illegally marketed is subject to enforcement at any time and that all unapproved drugs introduced onto the market after September 19, 2011, are subject to immediate enforcement action without prior notice and without respect to the enforcement priorities listed therein. See also 76 Fed. Reg. at 58399.

27. In May 2014, the United States conducted a seizure of certain unapproved and misbranded drugs that were being distributed by Ascend, including but not limited to the urea drug products that Defendants had manufactured for Ascend (Ascend Cream Urea 40% Cream, Ascend Urea Lotion 40%, and Ascend Urea Cream 39%). The United States notified Defendants of the seizure by letter dated May 15, 2014.

28. Defendant Bedard stated, by letter dated March 5, 2014 to FDA, that Crown "does not currently plan to file an NDA for any of these products . . . ." During FDA's February 2016 inspection, the firm's Vice President of Quality Assurance and Quality Control, stated that he believes that the products at issue are legal drug products and that they will continue to be manufactured and shipped in the future.

29. Accordingly, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (d), and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any drug, including but not limited to Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredients, unless and until an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, all Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), and Sodium Sulfacetamide, and any product labeled similarly to such products and containing the same active ingredient(s) in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect Defendants' place(s) of business and all

records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 1st day of March, 2017.

Respectfully submitted,

Of Counsel:

JEFFREY S. DAVIS
Acting General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Administration

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

SUSAN WILLIAMS
Associate Chief Counsel
U.S. Dept. of Health & Human Services
Office of the General Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: 301-348-3010

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

MICHAEL S. BLUME
Director
Consumer Protection Branch

/s/
MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., 6th Fl. South
Washington, DC 20001
Telephone: 202-307-0088
Fax: 202-514-8742
Megan.Englehart@usdoj.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. CROWN LABORATORIES, INC., a corporation and JEFFERY BEDARD, an individual, Defendants.	Civil Action No.: 2:17-cv-36 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Crown Laboratories, Inc., a corporation, and Jeffery Bedard, an individual (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. §§ 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. Introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce, manufacturing, processing, packaging, labeling, holding, or selling any Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide 10% & Sulfur 5% (hereafter, "Sodium Sulfacetamide"), or any drug labeled similarly to such drugs and containing the same active ingredient(s), unless and until an approved new drug application or an abbreviated new drug application or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs;

B. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is a new drug within the meaning of 21 U.S.C. § 321(p) and that is neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under to 21 U.S.C. § 355(i);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or directly or indirectly causing to be introduced or delivered for introduction, into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

D. Violating of 21 U.S.C. § 331(k) by, directly or indirectly, causing any drug that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Directly or indirectly causing to be done any act that results in the failure to implement and continuously maintain the requirements of this Decree.

Nothing in this paragraph or paragraph 7 or paragraph 9 shall preclude Defendants from marketing a drug subject to an ongoing Drug Efficacy Study Implementation (DESI) proceeding during the pendency of that proceeding. The preceding sentence does not apply when a DESI proceeding closes. No provision of this Decree shall affect the authority of the United States to bring an action against Defendants for a violation of the Act and/or its implementing regulations.

7. A. Within twenty (20) business days after entry of this Decree, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy all Rea Lo (Urea 40%) Cream, Rea Lo (Urea 40%) Lotion, Rea Lo 39 (Urea 39%) Cream, Dermasorb XM Complete Kit (Urea 39% Cream and Moisturizer), Sodium Sulfacetamide, any unapproved drug labeled similarly to such drugs and containing the same active ingredient(s), and any unapproved new drugs not expressly listed herein, in Defendants' custody, control, or possession (hereinafter, "Violative Drugs"). Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction.

B. Defendants shall at all times, until all of the Violative Drugs have been destroyed in accordance with this Decree, retain the Violative Drugs intact for examination or inspection by FDA at their facility at 349 Lafe Cox Drive, Johnson City, Tennessee ("the Facility"), and shall maintain all records or other proof necessary to establish the identity of the Violative Drugs to FDA's satisfaction. Defendants shall not cause the Violative Drugs to be

disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed.

C. Within fifteen (15) business days after receiving authorization from FDA to commence destroying the Violative Drugs, Defendants shall, under FDA supervision, complete the destruction in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in Paragraph 13, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

8. FDA shall be permitted, without prior notice and as FDA deems necessary, to make inspections of Defendants' place(s) of business (including, but not limited to, the Facility) and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other materials; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their respective components. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate

corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, selling, and/or distributing any or all unapproved or misbranded drugs;

B. Recall, at Defendants' expense, any drugs that are unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; or

F. Take any other corrective actions with respect to unapproved or misbranded drugs as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

10. Any order issued by FDA pursuant to Paragraph 9 shall be issued by the appropriate FDA District Director, and shall specify the deficiencies or violations giving rise to the order. Unless a different time frame is specified by FDA in its order, within five (5) business days after receiving an order pursuant to Paragraph 9, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking, or have undertaken, the specified corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and a proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

A. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

B. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order unless the Court stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this subparagraph shall be made in accordance with the terms set forth in Paragraph 19.

C. The process and procedures set forth in Paragraph 10.A-B shall not apply to any order issued under Paragraph 9 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while implementing the order.

11. Any action ordered pursuant to Paragraph 9 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. The cost of FDA's inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 9 shall be borne by Defendants at the rates specified in Paragraph 13.

12. The prohibitions set forth in Paragraphs 6 and 7 or in any order issued under Paragraph 9 shall not apply to any drug manufactured solely for export and/or exported from the United States, provided that all applicable requirements of the Act, including 21 U.S.C. §§ 381(e) and 382, and its implementing regulations have been satisfied with respect to such drug.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $90.65 per hour or fraction thereof per representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Facility, at any other location at which Defendants conduct business, and on Crown Laboratories, Inc.'s website, and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

15. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (hereafter collectively referred to as "Associated Persons"). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time any Defendant becomes associated

with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Crown Laboratories, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

18. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

19. All decisions specified in this Decree shall be vested in FDA's discretion and shall be final. If contested by Defendants, FDA's decisions under this Decree shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the case name and civil action number, be prominently marked "Decree Correspondence" and "Crown Laboratories, Inc." and be addressed to:

District Director
New Orleans District Office
U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2565

21. Should Defendants fail to comply with any provision of this Decree, then they shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues, an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation of this Decree, and an additional sum equal to three (3) times the retail value of each shipment of an unapproved new drug and/or a misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017.

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

JEFFERY BEDARD
Individually and on behalf of
Crown Laboratories, Inc.

For Plaintiff

CHAD A. READLER
Acting Assistant Attorney General
United States Department of Justice
Civil Division

MICHAEL S. BLUME
Director
Consumer Protection Branch

/s/

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., Suite 6400 South
Washington, DC 20001
Telephone: 202-307-0088
Fax: 202-514-8742
Megan.Englehart@usdoj.gov

24. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

SO ORDERED.

Dated this 25 day of July 2017

/s/

UNITED STATES DISTRICT JUDGE

Entry consented to

For Defendants

[redacted]

JEFFERY BEDARD
Individually and on behalf of
Crown Laboratories, Inc.

For Plaintiff

MARY M. ENGLEHART
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., Suite 6400 South
Washington, DC 20001
Telephone: 202-307-0088
Fax: 202-514-8742
Megan.Englehart@usdoj.gov

Daniel G. Jarcho
Attorney for Jeffery Bedard

Daniel G. Jarcho
Attorney for Crown Laboratories, Inc.

OF COUNSEL:

JEFFREY S. DAVIS
Acting General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
Food and Drug Division

SUSAN WILLIAMS
Associate Chief Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301-348-3010

Daniel G. Jarcho
Attorney for Jeffery Bedard

Daniel G. Jarcho
Attorney for Crown Laboratories, Inc.

OF COUNSEL:

[redacted]
Acting General Counsel
U.S. Dept. of Health & Human Services

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation
Food and Drug Division

SUSAN WILLIAMS
Associate Chief Counsel for Enforcement
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
301-348-3010

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
CROWN LABORATORIES, INC.	)	**BOARD OF PHARMACY**
	)	
Manufacturer Permit No. 192569	)	**CASE NO: 18-L-0111**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Crown Laboratories, Inc. (hereinafter referred to as "Crown") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. Counsel for the parties stipulate that Crown denies for all legal purposes other than this proceeding the allegations set forth in the Statement but further stipulate the Board would introduce sufficient evidence to prove Crown (a) entered into the Consent Decree of Permanent Injunction filed in the United States District Court, E.D. Tenn., 2:17-cv-36, dated July 26, 2017, and attached to the Statement (the "Consent Decree"), (b) is required to comply with the Consent Decree in that federal action, and (c) is required to comply with the Consent Decree as part of this Consent Order in this action.

2. Crown shall pay to the Board administrative costs in the amount of Ten Thousand dollars ($10,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be

dischargeable in bankruptcy and Crown shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Crown expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Crown further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Crown hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Crown agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Crown acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Crown acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the 11th day of July, 2019

Crown Laboratories, Inc.

By: J.S. Christie

J.S. "Chris" Christie, Jr.
Its: Attorney at Law

DONE this the 15th day of July, 2019

ALABAMA STATE BOARD OF PHARMACY

By: Kenny Sanders

Kenny Sanders, R.Ph., President

By: James S. Ward

James S. Ward
Its Attorney

Ward & Cooper, LLC
2100 South Bridge Parkway
Suite 580
Birmingham, Alabama 35209

CROWN
SKIN SCIENCE FOR LIFE

Arizona Disciplinary Action

On March 2, 2020, the Arizona Board of Pharmacy fully executed a Consent Agreement and Order for Civil Penalty (referred to as the "Consent Agreement") to resolve *In Matter of: Crown Laboratories, Inc. Manufacturer Permit No. M001475*, Case No. 20-0050 before the Arizona Board of Pharmacy. In the Consent Agreement, Crown agreed to pay a civil penalty for not reporting the change in ownership within the time frame specified in Arizona Administrative Code (A.A.C.) R4-23-601(F).

349 Lafe Cox Drive
Johnson City, TN 37604

www.crownlaboratories.com

Phone: (423) 926-4413
Fax: (423) 926-0165

MARK BRNOVICH
Attorney General
Firm State Bar No. 14000

JEANNE M. GALVIN
Assistant Attorney General
State Bar No. 015072
SETH T. HARGRAVES
Assistant Attorney General
State Bar No. 020176
2005 N. Central Ave., SGD/LES
Phoenix, Arizona 85004-1592
Tel: (602) 542-7983
Tel: (602) 542-7672
Fax: (602) 364-3202

Attorneys for the Arizona State Board of Pharmacy

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of **Crown Laboratories, Inc.** Applicant for Pending Permit No. M001475. As a Non-Resident Manufacturer In the State of Arizona. Applicant.	Board Case No. 20-0050 **CONSENT AGREEMENT AND ORDER FOR CIVIL PENALTY**

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and the responsibilities of the Arizona State Board of Pharmacy ("Board") under A.R.S. § 32-1901, *et. seq.*, Crown Laboratories, Inc. ("Applicant"), Applicant for issuance of Pending Non-Resident Manufacturer Permit no. M001475 in the State of Arizona and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as a final disposition of this matter.

RECITALS

1. Applicant has read and understands this Consent Agreement and has had the opportunity to discuss this Consent Agreement with an attorney, or has waived the opportunity to discuss this Consent Agreement with an attorney.

2. Applicant understands that it has a right to a public administrative hearing concerning this matter at which hearing it could present evidence and cross examine witnesses. By entering into this Consent Agreement, Applicant knowingly and voluntarily relinquishes all right to such an administrative hearing, as well as rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

3. Applicant affirmatively agrees that this Consent Agreement shall be irrevocable.

4. Applicant understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action by the Board against it.

5. Applicant understands this Consent Agreement deals with allegations of unprofessional conduct against Applicant. The investigation into these allegations against Applicant shall be concluded upon the Board's adoption of this Consent Agreement.

6. Applicant understands that this Consent Agreement does not constitute a dismissal or resolution of any other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding.

7. Applicant also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision, or officer of this State from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

8. Applicant acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, it may not revoke its acceptance of the Consent Agreement or make any modifications to the document. Any modification to this original document is ineffective and void unless mutually agreed by the parties in writing.

9. This Consent Agreement is subject to the approval of the Board and is effective only when accepted by the Board and signed by the Executive Director. In the event that the Board does not approve this Consent Agreement, it is withdrawn and shall be of no evidentiary value and shall not be relied upon nor introduced in any action by any party, except that the parties agree that should the Board reject this Consent Agreement and this case proceeds to hearing, Applicant shall assert no claim that the Board was prejudiced by its review and discussion of this document or any records relating thereto.

10. If a court of competent jurisdiction rules that any part of this Consent Agreement is void or otherwise unenforceable, the remainder of the Consent Agreement shall remain in full force and effect.

11. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board and may be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

12. The parties understand and agree that Portable Document Format and facsimile copies of this Consent Agreement including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. Applicant understands that any violation of this Consent Agreement constitutes unprofessional conduct and may result in disciplinary action. A.R.S. §§ 32-1901.01(A)(19) and A.R.S. § - 1927.02(A)(1).

14. Applicant agrees that the Board will adopt the following Findings of Fact, Conclusions of Law and Order.

ACCEPTED AND AGREED BY APPLICANT

Marii Fagatie Dated: 02/26/2020

On behalf of Crown Laboratories, Inc.

FINDINGS OF FACT

1. The Board is the duly constituted authority for licensing and regulating the practice of pharmacy in the State of Arizona.

2. Applicant is seeking the issuance of permit number M001475, which will allow it to operate as a Non-Resident Manufacturer in the State of Arizona. Applicant is located at 349 Lafe Cox Drive, Johnson City, TN 37604.

3. Applicant previously held Manufacturer Permit no. M000641 under prior ownership, which was initially issued on October 7, 2013.

4. The Board possesses jurisdiction over the subject matter and over Applicant pursuant to A.R.S. § 32-1901 *et seq.*

5. Pursuant to Arizona Administrative Code (A.A.C.) R4-23-601(F), at least 14 days before a change in ownership of a permit, the new permittee shall apply to the Board for a new license or permit.

6. On October 2, 2019, Board staff received a change of ownership application for pharmacy permit number M00641. According to documentation obtained

by the Board, the change of ownership had occurred on January 16, 2018.

CONCLUSIONS OF LAW

1. The Board possesses subject matter and personal jurisdiction over Applicant pursuant to A.R.S. § 32-1901 *et seq*.

2. The Board may deny a permit to an applicant that has engaged in unprofessional conduct. A.R.S. § 32-1927.02(P).

3. The conduct and circumstances described above constitutes unprofessional conduct pursuant to A.R.S. § 32-1901.01(A)(18) (violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of the Pharmacy Act) as it relates to A.A.C. R4-23-601(F) and A.A.C. R4-23-607(D) (which requires non-resident permittees to make application to the Board at least 14 days before there is a change in ownership).

ORDER

Based on the Findings of Fact and Conclusions of Law and pursuant to the authority granted to the Board under A.R.S. § 32-1927.02:

1. **IT IS HEREBY ORDERED** Applicant shall pay to the Board as a civil penalty the sum of Two Hundred Fifty Dollars (**$250.00**). The civil penalty shall be paid in full to the Board within **sixty (60) days** of the effective date of this Consent Agreement and Order. The effective date of this Consent Agreement is the date it is signed by the Board's Executive Director.

2. **The permit shall not issue until such time Applicant pays the civil penalty as set forth above.** Within five (5) business days of the receipt of the $250.00 civil penalty, the Board shall issue Applicant a Non-Resident Manufacturer Permit.

3. **Should Applicant fail to pay the civil penalty as set forth above within sixty (60) days of the effective date of the Consent Agreement and Order, the**

application shall automatically be denied. The effective date of this Consent Agreement and Order is the date it is signed by the Board's Executive Director or his designee.

4. Applicant understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action.

5. If Applicant violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Applicant notice and the opportunity to be heard, may revoke, suspend or take other disciplinary actions against Applicant's permit. The issue at such a hearing will be limited solely to whether this Order has been violated.

DATED this 2nd day of March, 2020.

ARIZONA STATE BOARD OF PHARMACY

By: Elizabeth Dodge, Deputy Director for
KAMLESH GANDHI, PharmD
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 2nd day of March, 2020, with:

Arizona State Board of Pharmacy
1616 W. Adams Street
Phoenix, Arizona 85007

COPY OF THE FOREGOING MAILED
BY CERTIFIED & REGULAR FIRST-CLASS MAIL
this 2nd day of March, 2020, to:

Crown Laboratories, Inc.
349 Lafe Cox Drive
Johnson City, TN 37604

15C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Wholesaler or ☐ Ownership Change (Provide current license number if making changes: WH_____

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1,2,3,4
☐ Partnership - Pages 1,2,3,7
☒ Non Publicly Traded Corporation – Pages 1,2,3,5,6
☐ Sole Owner – Pages 1,2,3,8

GENERAL INFORMATION to be completed be all types of ownership

Facility Name: Solaris Pharma Corporation

Physical Address: 1031 RT 202-206, Suite G-200,

City: Bridgewater State: NJ Zip Code: 08807

Telephone Number: 908-800-0300 Fax Number: _____

Toll Free Number: _____

E-mail: info@solaris-pharma.com Website: https://www.solaris-pharma.com/

Facility Manager: Shalin Jani

Professional qualifications and experience of facility manager: See Attached resume

Types of licensed outlets or authorized persons firm will serve:

☒ Pharmacies ☐ Practitioners ☐ Hospitals ☒ Wholesalers
☐ Other: _____

Type of Products to be handled or wholesaled by firm:

☒ Legend Pharmaceuticals, Supplies or Devices
☐ Poisons or Chemicals
☐ Controlled Substances (include copy of DEA)
☐ Other: _____
☐ Hypodermic Devices
☐ Veterinary Legend Drugs

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership

Is your company VAWD certified by NABP? Yes ☐ No ☒
(If yes, provide a copy of the certificate)

Licensed as Manufacturer by the FDA? ~~Yes~~ ☒ No ☒
(If yes, provide a copy of your FDA registration)

SJ - not registered as mfg.

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☒

List the top 4 suppliers your company has been associated with regards to pharmaceutical products that were sold, dispensed or distributed with the last year.

Name: N/A - Virtual manufacturer that will sell to wholesalers. We are expecting FDA approval in June/July 2020 of the first Product to launch under the Solaris label.
Address:

Name:
Address:

Name:
Address:

Name:
Address:

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

This page must be submitted for all types of ownership.

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Shalin Jani
Print Name of Authorized Person

5/26/2020
Date

Board Use Only	Date Processed:_____	Amount: 500.00

APPLICATION FOR OUT-OF-STATE WHOLESALER LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: New Jersey

Parent Company if any: _____

Mailing Address: 1031 Route 202/206, Suite G-200,

City: Bridgewater State: NJ Zip: 08807

Telephone: 908-800-0300 Fax: _____

Contact Person: Shalin Jani

For any corporation non-publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Srinivasan Raghavan 1031 Route 202/206, Suite G-200, Bridgewater New Jersey 08807
Name Business Address

b) Shalin Jani 1031 Route 202/206, Suite G-200, Bridgewater New Jersey 08807
Name Business Address

c) Satish Pejaver 1031 Route 202/206, Suite G-200, Bridgewater New Jersey 08807
Name Business Address

d) Rajani Pejaver 1031 Route 202/206, Suite G-200, Bridgewater New Jersey 08807
Name Business Address

2) Provide the number of shares issued by the corporation. 21,450,000

3) What was the price paid per share? $1.00

A Nevada business license is not required, however if the wholesaler has a Nevada business license please provide the number: _____

Include with the application for a non-publicly traded corporation

List of officers and directors

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

SHALIN JANI

Jamison, PA [redacted]

Pharmaceutical executive with deep, cross functional experience and proven track record of success. Successfully build teams across multiple functional areas driving growth and actualizing organizational strategic vision.

- Joined Solaris and helped company through two funding rounds while heading the Business Operations and Regulatory Affairs groups
- Redesigned company portfolio to be more robust during generic downturn and infused the pipeline with high barrier products while managing cost of development through innovative clinical and regulatory strategies
- Established key partnerships with distributors, contract manufactures, and suppliers

EXPERIENCE

FEB 2017 – PRESENT

VP, OPERATIONS & RA, SOLARIS PHARMA

Head of commercial and R&D operations and regulatory affairs with functional responsibilities for the overall P&L and corporate strategy of the company with direct responsibility for portfolio, procurement, alliance management, business development, licensing, supply chain, launch management, sales and marketing, and regulatory affairs

JAN 2016 – FEB 2017

LEAD PORTFOLIO & PROGRAM MANAGEMENT, PFIZER

Lead a large sterile injectable portfolio containing complex injectable products including drug-device combination products

APRIL 2005 – DEC 2015

VARIOUS ROLES OF INCREASING RESPONSIBILITIES, TEVA, SANDOZ, G&W LABS & ACTAVIS

Managed clinical, regulatory, and technical functions across multiple dosage forms and supported many development programs, approvals, and launches on both branded and generic development platforms.

EDUCATION

MS CELL & DEVELOPMENTAL BIOLOGY, UMDNJ/RUTGERS UNIVERSITY

BS MOLECULAR BIOLOGY & BIOCHEMISTRY, RUTGERS UNIVERSITY

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

SOLARIS PHARMA CORPORATION
0400696925

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 22, 2014.

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

I further certify that the registered agent and office are:

SRINIVASAN RAGHAVAN
1031 ROUTE 202-206
SUITE G-200
BRIDGEWATER, NJ 08807

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 11th day of November, 2020

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6112798743

Verify this certificate online at

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

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

SOLARIS PHARMA CORPORATION
0400696925

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 22, 2014.

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

I further certify that the registered agent and office are:

SRINIVASAN RAGHAVAN
1031 ROUTE 202-206
SUITE G-200
BRIDGEWATER, NJ 08807

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 19th day of May ,2020

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6105104540

Verify this certificate online at

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

Need updated COGS

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 4/19/2021

Registration Number: 5005725 **Registered as:** Manufacturer and Wholesale

Parent Company Name: SOLARIS PHARMA CORPORATION

Trade Name:

Original Issue Date: 01/22/2020 **Expiration Date:** 01/31/2022

Current Issue Date: 03/05/2021

Disciplines: No

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0739222

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

1031 ROUTE 202/206, STE G-200 BRIDGEWATER, NJ 08807-

Reg. No.
5005725

SOLARIS PHARMA CORPORATION
1031 ROUTE 202/206, STE G-200
BRIDGEWATER, NJ 08807-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2021

Establishment Copy

Corporate Officers:

Srinivasan Raghavan, 1031 Route 202/206, Suite G-200, Bridgewater NJ 08807, SSN, [redacted], President and Treasurer

Shalin Jani, 1031 Route 202/206, Suite G-200, Bridgewater NJ 08807, SSN, [redacted], Vice-President and Secretary

Satish Pejaver, 1031 Route 202/206, Suite G-200, Bridgewater NJ 08807, SSN, [redacted], CEO

Shareholders over 10%

Srinivasan Raghavan, 1031 Route 202/206, Suite G-200, Bridgewater NJ 08807, SSN, [redacted], President and Treasurer

Athos Service GmbH, Rosenheimer Platz 6, 81669 Munich, Germany

Hampl Family Trust, 1265 Bayshore Drive, Englewood, FL 34223

Solaris Pharma Corporation is located in a office compound which requires badge access to enter. Employee badge access is also required to enter the Solaris Pharma Corporation offices. Two security guard patrol the premises 24/7, 365 days a year ensuring a safe and secure office.

Please note that as a virtual manufacturer, at no point in time do we physically store/hold drug product.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 10114685

Application/License No. _____

SOLARIS PHARMA CORPORATION (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1031 ROUTE 202-206, SUITE G200, Bridgewater, New Jersey, 08807 (Address of Applicant/Principal), as PRINCIPAL, and Hudson Insurance Company (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1035 Greenwood Boulevard, Suite 265 LAKE MARY Florida 32746 United States (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Nov 11, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 13th day of November, 20 20.

APPLICANT/PRINCIPAL
SOLARIS PHARMA CORPORATION
COMPANY

Authorized Representative

SURETY
Hudson Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

Hudson Insurance Company CORPORATE SEAL 1918 DELAWARE B307

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Bond Number: 10114685

HUDSON INSURANCE GROUP

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

John D. Weisbrot; Patricia A. Tinsman; Steven M. Varga; Melissa L.

McDade of the State of Pennsylvania

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

one hundred thousand dollars

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly authorized, on this 16th day of November, 20 17 at New York, New York.

(Corporate seal)

HUDSON INSURANCE COMPANY

Attest.....
Dina Daskalakis
Corporate Secretary

By.....
Michael P. Cifone
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

On the 16th day of November, 20 17 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of HUDSON INSURANCE COMPANY, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY
NOTARY PUBLIC
STATE OF NEW YORK

.....
ANN M. MURPHY
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2021

CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.:

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 13th day of November, 20 20.

(Corporate seal)

SEAL 1918

By.....
Dina Daskalakis, Corporate Secretary

www.verifysuretybond.org

To verify the bond please visit https://www.suretybond.org/validate/?code=d1ZC1BgV08RVgFd1BdXl0MeA

HUDSON INSURANCE COMPANY

SHORT FORM FINANCIAL STATEMENT
AS OF DECEMBER 31, 2019

ASSETS

Bonds	$	345,619,567
Real estate		0
Cash on hand and on deposit		111,338,436
Reinsurance Receivable		356,648,283
FIT recoverable (including net deferred tax asset)		16,352,414
Aggregate write-ins for other than invested assets		374,021,233
Deferred premiums, agents' balances and installments booked but deferred and not yet due (including earned but unbilled premiums)		68,255,801
Stocks		254,859,465
Other Assets		89,769,150
Total Assets	$	1,616,864,349

LIABILITIES & SURPLUS

Losses	$	232,135,659
Loss adjustment expense		27,181,246
Other expenses		27,548,056
Unearned Premiums		113,141,748
Ceded reinsurance premiums payable		605,079,295
Payable to parent, subsidiaries and affiliates		4,826,344
Commissions payable, contingent commissions and other similar charges		22,657,806
Other Liabilities		107,140,820
Total Liabilities	$	1,139,710,974
Preferred and Common capital stock	$	7,500,238
Gross paid in and contributed surplus		293,480,097
Unassigned funds (surplus)		176,173,040
Surplus as regards policyholders	$	477,153,375
Total Liabilities and Surplus	$	1,616,864,349

STATE OF NEW YORK)
) ss:
COUNTY OF NEW YORK)

I, the undersigned Senior Vice President and Controller of Hudson Insurance Company hereby certify the foregoing to be a short form financial statement in the form of a balance sheet, showing the Company's assets and liabilities on a provisional basis, at the close of business on December 31, 2019.

IN TESTIMONY WHEREOF, I have set my hand and affixed the seal of the Company, this 24TH day of MARCH, 2020.

Keith Brennan
Keith M. Brennan
Controller

Subscribed and sworn to before me this 24TH day of MARCH, 2020.
My commission expires

CAMERON GOURLAY
Notary Public, State of New York
No. 01GO6372305
Qualified in New York County
Commission Expires June 4, 2022

CAMERON GOURLAY
NOTARY PUBLIC
STATE OF NEW YORK

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **solaris**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Solaris Pharma Corporation	3012158090	079904672	ANALYSIS;	1031 Route 202/206 Ste 200, Bridgewater, New Jersey (NJ) 08807, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Friday, Apr 24, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

California State Board of Pharmacy
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

WHOLESALER or NONRESIDENT WHOLESALER SURETY BOND

Business and Professions Code Sections 4162, 4162.5

Bond No. 3325785

Application/License No. NA

KNOW ALL PERSONS BY THESE PRESENTS:

That, SOLARIS PHARMA CORPORATION (Applicant), doing business as a wholesaler, whose address for purposes of service is 1031 ROUTE 202-206, SUITE G200, Bridgewater, New Jersey, 08807 (address of Applicant), as PRINCIPAL, and Great American Insurance Company (Surety Company), a corporation organized under the laws of Ohio (state of incorporation) and authorized to transact a general surety business in the State of California, whose address for purposes of service is, 301 E 4th Street CINCINNATI Ohio 45202 United States (address for Surety Company) as SURETY, are held and firmly bound unto the People of the State of California, and to the Pharmacy Board Contingent Fund, for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Apr 09, 2020 (effective date)

WHEREAS, the provisions of Sections 4162 and/or 4162.5, Business and Professions Code, require that the Applicant file or have on file with the California State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Pharmacy Board Contingent Fund, and this bond is executed and tendered in accordance therewith. The purpose of the bond is to secure payment of any administrative fines imposed on Applicant by the Board, and/or any cost recovery owed by Applicant to the Board under Business and Professions Code Section 125.3.

NOW THEREFORE, the conditions of the foregoing obligation are that if the Applicant shall comply with and be subject to the provisions of Division 2, Chapter 9 (commencing with Section 4000) of the Business and Professions Code, then this obligation shall be null and void; otherwise it shall remain in full force and effect.

PROVIDED HOWEVER, this bond is subject to the following express conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant and the Surety to comply with the provisions of Division 2, Chapter 9 (commencing with Section 4000) of the Business and Professions Code and of Chapter 2, Title 14, Part 2 (commencing with Section 995.010) of the Code of Civil Procedure and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond, in conformity with Chapter 2, Title 14, Part 2 (commencing with Section 995.010) of the Code of Civil Procedure and Division 2, Chapter 9 (commencing with Section 4000) of the Business and Professions Code.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in Business and Professions Code Sections 4162 and 4162.5. The Board may make a claim against the bond for any administrative fine imposed on Applicant by the Board pursuant to Division 2, Chapter 9 (commencing with Section 4000) of the Business and Professions Code, or for any cost recovery ordered payable by Applicant pursuant to Business and Professions Code Section 125.3, if Applicant fails to pay to the Board the fine or cost recovery within thirty (30) days of the order imposing the fine or cost recovery. Any such claim may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Pharmacy Board Contingent Fund.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may be cancelled by the Surety in accordance with the provisions of Article 13 (commencing with Section 996.310), Chapter 2, Title 14, Part 2 of the Code of Civil Procedure.

(7) The Applicant and Surety may be served with notices, papers and other documents under the provisions of Chapter 2, Title 14, Part 2 (commencing with Section 995.010) of the Code of Civil Procedure at the addresses given above.

I certify (or declare) under penalty of perjury, under the laws of the State of California, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10th day of April, 20 20.

☐ PRESCRIPTION DRUG WHOLESALER
or
☑ OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER

Principal's Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Surety Company's Representative

John D. Weisbrot, *Attorney-in-Fact*
print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
California Resident Agent

GREAT AMERICAN INSURANCE COMPANY

GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by
this power of attorney is not more than THREE

No. 0 21243

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below, each individually if more than one is named, its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below.

Name	Address	Limit of Power
JOHN D. WEISBROT MELISSA L. MCDADE STEVEN M. VARGA	ALL OF PIPERSVILLE, PENNSYLVANIA	ALL $10,000,000

This Power of Attorney revokes all previous powers issued on behalf of the attorney(s)-in-fact named above.

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 13TH day of DECEMBER , 2018 .

Attest

GREAT AMERICAN INSURANCE COMPANY

Assistant Secretary

Divisional Senior Vice President

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 13TH day of DECEMBER 2018 before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument, that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

Susan A. Kohorst
Notary Public, State of Ohio
My Commission Expires 05-18-2020

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.

RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 10th day of April . 2020 .

Assistant Secretary

To verify the bond please visit https://www.suretybond.org/validate/?code=e1pV1WEl1kBVcHekVSRQ9WcA

GREAT AMERICAN INSURANCE GROUP

301 East Fourth Street
16th Floor
Cincinnati, OH 45202

GAIG.com

GREAT AMERICAN INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND CAPITAL & SURPLUS
AS OF DECEMBER 31, 2018

ADMITTED ASSETS		LIABILITIES, CAPITAL AND SURPLUS		
Bonds	$ 3,874,400,270	Unpaid losses and loss expenses		$ 3,789,091,910
Stocks	1,257,698,534	Reserve for underwriting expenses		275,457,294
Mortgage loans on real estate	325,454,841	Federal and foreign income taxes		5,335,703
Real estate (net of encumbrances)	58,221,275	Reserve for unearned premiums		1,343,186,228
Cash and short-term investments	318,171,232	Ceded reinsurance premiums payable		111,234,346
Other invested assets	594,596,935	Funds held under reinsurance treaties		521,260,285
Receivable for securities	1,021,461	Retroactive reinsurance ceded		(144,437,953)
Investment income due and accrued	35,251,279	Other liabilities		219,050,289
Agents' and premium balances	601,673,429	Total liabilities		6,120,178,102
Reinsurance recoverable on loss and loss expense payments	65,592,566			
Net deferred tax asset	163,195,781			
Receivable from affiliates	10,011,326	Capital stock	$ 15,440,600	
Receivable from Federal Crop Insurance Corporation	466,667,511	Paid in surplus	809,251,710	
Company owned life insurance	179,861,963	Special surplus funds	102,620,000	
Funds held as collateral	10,213,307	Unassigned funds	978,604,624	
Funded deductibles	28,192,144	Policyholders' surplus		1,905,916,934
Other admitted assets	35,871,182			
Total	$ 8,026,095,036	Total		$ 8,026,095,036

Securities have been valued on the basis prescribed by the National Association of Insurance Commissioners.

STATE OF OHIO

SS.:

COUNTY OF HAMILTON

Robert J. Schwartz, Vice President and Controller, and Stephen Beraha, Assistant Vice President and Assistant Secretary, being duly sworn, each for himself deposes and says that they are the above described officers of the Great American Insurance Company of Cincinnati, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety by virtue of the laws of the State of Ohio and has duly complied with all the requirements of the laws of said state applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under Public Law 97-258 enacted September 13, 1982 (96 Stat. 1047 as amended: 31 U.S.C. 9304-9308); that to the best of their knowledge and belief the above statement is a full, true and correct Statement of the Assets, Liabilities and Capital & Surplus of the said Company as of December 31, 2018

Subscribed and sworn to before me

this 18th day of February, 2019

NOTARIAL SEAL STATE OF OHIO

Controller

Assistant Secretary

Public Notary

JENNIFER A. MEYER
Notary Public, State of Ohio
My Commission Expires 11-08-2021

ACKNOWLEDGMENT

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

State of Pennsylvania
County of BUCKS)

On April 10, 2020 before me, Lisa M. Grimsley, Notary Public
(insert name and title of the officer)

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

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

WITNESS my hand and official seal.

Signature _____ (Seal)

Commonwealth of Pennsylvania - Notary Seal
Lisa M. Grimsley, Notary Public
Bucks County
My commission expires September 28, 2022
Commission number 1257775
Member, Pennsylvania Association of Notaries

ACKNOWLEDGMENT

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

State of ~~California~~ NEW JERSEY
County of SOMERSET)

On May 13, 2020 before me, RUTH MARRERO, Notary Public
(insert name and title of the officer)

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

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

WITNESS my hand and official seal.

Signature Ruth Marrero (Seal)

RUTH MARRERO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires Dec. 14, 2021

16

16A

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☐ Partnership - Pages 1-3 & 6
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Empower Pharmacy

Physical Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip Code: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Toll Free Number: (877) 562-8577 (Required per NAC 639.708)

E-mail: shaunnoorian@gmail.com Website: empowerpharmacy.com

Supervising Pharmacist: Jordan Cuccia Nevada License #: ~~Pending~~ 20531 ✓ 10/31/21

SERVICES PROVIDED

Yes	No	
☑	☐	Parenteral
☑	☐	Sterile Compounding
☑	☐	Non Sterile Compounding
☑	☐	Mail Service Sterile Compounding
☐	☑	Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3011887629

Please provide the name of the facility as registered with the FDA and the registration number:
Empower Pharmacy / 3011887629

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Empower Pharmacy

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Jordan Cuccia Nevada License Number: 20531

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☑ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.
The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Shaun Noorian
Print Name of Authorized Person

5/18/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Texas

Parent Company if any: Empower Clinic Services, LLC

Address: 5980 W Sam Houston Pkwy N Ste 300

City: Houston State: TX Zip: 77041

Telephone: (832) 678-4417 Fax: (832) 678-4419

Contact Person: Shaun Noorian

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Shaun Noorian 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1

3) What was the price paid per share? $25,000

4) What date did the corporation actually receive the cash assets? 1/14/2009

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

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

EMPOWER PHARMACY
5980 W SAM HOUSTON PKY N STE 300
HOUSTON TX 77041

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

EMPOWER CLINIC SERVICES LLC DBA
EMPOWER PHARMACY
5980 W SAM HOUSTON PKY N STE 300
HOUSTON, TX 77041

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

PRESCRIPTION DRUG MANUFACTURER

License # 1001983
Expires: July 6, 2022

NON-TRANSFERABLE

John Hellerstedt
Commissioner

513228

Re: Ownership

Company Name: Empower Clinic Services, LLC
Doing Business As: Empower Pharmacy

Name: Shaun Noorian
DOB: [redacted]
Titles: CEO, Business owner, LLC manager, LLC officer, Sole shareholder
Residential Address: [redacted] Kelliwood Oaks Dr, Katy, TX 77450
Business Address: 5980 W Sam Houston Pkwy N Ste 300, Houston, TX 77041
Business Phone: (832) 678-4417
Home Phone: [redacted]
Ownership: 100%

Franchise Tax Account Status

As of : 05/07/2021 13:18:57

This page is valid for most business transactions but is not sufficient for filings with the Secretary of State

EMPOWER CLINIC SERVICES, L.L.C.	
Texas Taxpayer Number	32038504513
Mailing Address	5980 W SAM HOUSTON PKWY N STE 300 HOUSTON, TX 77041-5251
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	12/12/2008
Texas SOS File Number	0801062724
Registered Agent Name	SHAUN NOORIAN
Registered Office Street Address	5980 W SAM HOUSTON PKWY N STE 300 HOUSTON, TX 77041

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

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Empower Clinic Services, L.L.C. (file number 801062724), a Domestic Limited Liability Company (LLC), was filed in this office on December 12, 2008.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on May 15, 2020.

Ruth R. Hughs
Secretary of State

Maria Herrera

From: Shaun Noorian <[redacted]
Sent: Friday, May 7, 2021 1:40 PM
To: Maria Herrera
Subject: Re: Nevada Board of Pharmacy - Application (Empower Pharmacy)
Attachments: Taxable Entity Search Results.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Hello Maria,

I spoke with a representative from the Texas Secretary of State and they confirmed that they no longer use Certificates of Account Status. This document has been replaced with the Taxable Entity Search. I attached an additional document showing the results of this public Taxable Entity Search that shows that we are current with all state franchise taxes. Please let me know if there's anything else I can get for you.

Thanks,

Shaun Noorian Founder & CEO
Mobile: (281) 804-4499
Empower Pharmacy *Expanding Access.*

On Fri, May 7, 2021 at 10:02 AM Maria Herrera <m.herrera@pharmacy.nv.gov> wrote:

> Hi Shaun,
>
> Mark asked me to finalize a few applications to get them set on the scheduled June Board Meeting, and I came upon yours. The only thing we were not sure of is the Certificate of Good Standing you provided has "Certificate of Fact" written on it and it does not state "Certificate of Good Standing" or that all documents and fees have been paid with the Secretary of State? is this one in the same in Texas? Can you provide something from the state of Texas stating that this is One in the same?
>
> Thank you,
>
> Maria Herrera
>
> Licensing Specialist
>
> Nevada State Board of Pharmacy

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

Ruth R. Hughs
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Empower Clinic Services, L.L.C. (file number 801062724), a Domestic Limited Liability Company (LLC), was filed in this office on December 12, 2008.

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

It is further certified that our records indicate SHAUN NOORIAN as the designated registered agent for the above named entity and the designated registered office for said entity is as follows:

5980 W SAM HOUSTON PKWY N
STE 300
HOUSTON, TX - 77041 USA

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on April 25, 2021.

Ruth R. Hughs
Secretary of State

MEMBERSHIP LISTING

	NAME OF MEMBER	PLACE OF RESIDENCE	TIME BECAME OWNER	CERTIFICATES ISSUED		FROM WHOM CERTIFICATES WERE TRANSFERRED (If Original Issue Enter As Such)
				CERTIF. NOS.	MEMBERSHIP %	
	Shaun Noorian	[redacted] Kelliwood	12/12/08	00	100	Original
		Oaks Dr				
A		Katy, TX 77450				
B						
C						
D						
E						
F						
G						

CERTIFICATE No. 00

DATED Jan 14, 2009

RECEIVED CERTIFICATE No. _____

FOR 100 PERCENTAGE INTEREST

ON _____

ISSUED TO

NAME _____

ADDRESS _____

00 | ORGANIZED UNDER THE LAWS OF THE STATE OF TEXAS | PERCENTAGE INTEREST 100

Percentage Interest

Empower Clinic Services, L.L.C.

A LIMITED LIABILITY COMPANY

This Certifies That Shaun Noorian *is the owner*

of 100 *Percentage Interest of the above Limited Liability Company transferable only on the books of the Limited Liability Company by the holder hereof in person or by duly authorized attorney upon surrender of this Certificate properly endorsed, and is entitled to the full benefits and privileges of such membership subject to the duties and obligations, as more fully set forth in the Company's Certificate of Formation/Operating Agreement/Regulations for this Limited Liability Company. Transfer of this Percentage Interest is subject to restrictions in the books of the Limited Liability Company.*

In Witness Whereof, *The said Limited Liability Company has caused this Certificate to be executed by its duly authorized Member(s)/Manager(s) and its Limited Liability Company Seal to be hereunto affixed, this* 14th *day of* Jan *A.D.,* 2009

Shaun Noorian

Shaun Noorian

©FASTKIT

This Document Contains Security Features See back For Details

2774

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 12-19-2008

Employer Identification Number:
26-3899110

Form: SS-4

Number of this notice: CP 575 A

EMPOWER CLINIC SERVICES LLC
SHAUN NOORIAN MBR
1402 KELLIWOOD OAKS DR
KATY, TX 77450

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 26-3899110. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear off stub and return it to us.

Based on the information received from you or your representative, you must file the following form(s) by the date(s) shown.

Form 941	04/30/2009
Form 940	01/31/2010
Form 1065	04/15/2009

If you have questions about the form(s) or the due date(s) shown, you can call us at the phone number or write to us at the address shown at the top of this notice. If you need help in determining your annual accounting period (tax year), see Publication 538, *Accounting Periods and Methods*.

We assigned you a tax classification based on information obtained from you or your representative. It is not a legal determination of your tax classification, and is not binding on the IRS. If you want a legal determination of your tax classification, you may request a private letter ruling from the IRS under the guidelines in Revenue Procedure 2004-1, 2004-1 I.R.B. 1 (or superseding Revenue Procedure for the year at issue). Note: Certain tax classification elections can be requested by filing Form 8832, *Entity Classification Election*. See Form 8832 and its instructions for additional information.

A limited liability company (LLC) may file Form 8832, *Entity Classification Election*, and elect to be classified as an association taxable as a corporation. If the LLC is eligible to be treated as a corporation that meets certain tests and it will be electing S corporation status, it must timely file Form 2553, *Election by a Small Business Corporation*. The LLC will be treated as a corporation as of the effective date of the S corporation election and does not need to file Form 8832.

(IRS USE ONLY) 575A 12-19-2008 EMPO B 9999999999 SS-4

If you are required to deposit for employment taxes (Forms 941, 943, 940, 944, 945, CT-1, or 1042), excise taxes (Form 720), or income taxes (Form 1120), you will receive a Welcome Package shortly, which includes instructions for making your deposits electronically through the Electronic Federal Tax Payment System (EFTPS). A Personal Identification Number (PIN) for EFTPS will also be sent to you under separate cover. Please activate the PIN once you receive it, even if you have requested the services of a tax professional or representative. For more information about EFTPS, refer to Publication 966, *Electronic Choices to Pay All Your Federal Taxes* and Publication 4248, *EFTPS (Brochure)*. If you need to make a deposit before you receive your Welcome Package, please visit an IRS taxpayer assistance center to obtain a Federal Tax Deposit Coupon, Form 8109-B. To locate the taxpayer assistance center nearest you, visit the IRS Web site at http://www.irs.gov/localcontacts/index.html. Note: You will not be able to obtain Form 8109-B by calling 1-800-829-TAXFORMS (1-800-829-3676).

The IRS is committed to helping all taxpayers comply with their tax filing obligations. If you need help completing your returns or meeting your tax obligations, Authorized e-file Providers, such as Reporting Agents (payroll service providers) are available to assist you. Visit the IRS Web site at www.irs.gov for a list of companies that offer IRS e-file for business products and services. The list provides addresses, telephone numbers, and links to their Web sites.

To obtain tax forms and publications, including those referenced in this notice, visit our Web site at www.irs.gov. If you do not have access to the Internet, call 1-800-829-3676 (TTY/TDD 1-800-829-4059) or visit your local IRS office.

IMPORTANT REMINDERS:

* Keep a copy of this notice in your permanent records. **This notice is issued only one time and the IRS will not be able to generate a duplicate copy for you.**
* Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.
* Refer to this EIN on your tax-related correspondence and documents.

If you have questions about your EIN, you can call us at the phone number or write to us at the address shown at the top of this notice. If you write, please tear off the stub at the bottom of this notice and send it along with your letter. If you do not need to write us, do not complete and return the stub. Thank you for your cooperation.

Keep this part for your records. CP 575 A (Rev. 7-2007)

Return this part with any correspondence so we may identify your account. Please correct any errors in your name or address.

CP 575 A

9999999999

Your Telephone Number ( ) -

Best Time to Call

DATE OF THIS NOTICE: 12-19-2008
EMPLOYER IDENTIFICATION NUMBER: 26-3899110
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

EMPOWER CLINIC SERVICES LLC
SHAUN NOORIAN MBR
1402 KELLIWOOD OAKS DR
KATY, TX 77450

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE COMPLAINT AGAINST:	)	
Empower Pharmacy (99-7594)	)	**Case No. 1510**
5980 W. Sam Houston Pkwy, Ste 300	)	
Houston, TX 77041	)	

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on June 13, 2018, before the Oklahoma State Board of Pharmacy ("Board"). Board members St. Cyr, Dudley, Spoon, Wilson, Adams, and Whitehead were present. President Whitehead presided. John M. Settle, Assistant Attorney General, served as prosecutor for the Board. Respondent appeared and was represented by legal counsel, Doug Rice of Derryberry & Naifeh, LLP.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of the right to contest the allegations of the Complaint herein, to cross-examine witnesses, and to present witnesses and evidence in defense of the allegations of the Complaint. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent is licensed as a non-resident pharmacy in the State of Oklahoma and is located at 5980 W. Sam Houston Pkwy, Ste 300, Houston, TX 77041. Souchinda Nanthavongdouangsy, D.Ph. #15854, is Respondent's pharmacist-in-charge.

2. Respondent compounded the following products that the Board alleges are commercially available or essentially copies of commercially available FDA-approved drug products under Oklahoma law:

HCG 11,000 units/vial & units/vial kits	#287 prescriptions
HCG 5,000 units/vial & units/vial kits	#85 prescriptions

HCG injection in 5,000 units per vial is commercially available. HCG injection in 11,000 units per vial is essentially a copy of the HCG 10,000 units/vial.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.

2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.

3. Respondent has neither admitted nor denied violating OAC 535:15-10-53(a) by compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product, as set forth in Counts 1 through 372 of the First Amended Complaint.

4. Pursuant to 59 O.S. §353.7(12), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed Three Thousand Dollars ($3000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired. The Board may also impose as part of any disciplinary action the payment of costs expended by the Board for any legal fees and costs, including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees.

AGREED ORDER

1. Respondent, Empower Pharmacy, a non-resident pharmacy in the State of Oklahoma and holder of non-resident pharmacy license number 99-7594, neither admits nor denies guilt on all Three Hundred Seventy-two (372) Counts. In order to resolve this dispute outside of a hearing on the merits, however, Respondent agrees as follows:

2. Respondent is hereby fined One Hundred and no/100 Dollars ($100.00) for each Count 1 through 372 of the Complaint for a total fine on said Counts 1 through 372 of Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00).

3. The total amount of fines due from Respondent is Thirty-seven Thousand Two Hundred and no/1 00 Dollars ($37,200.00). This fine is due on June 13, 2018.

4. This Agreed Order is not considered "discipline" by the Board, but instead is a deferral of the same pending a probationary period of two years. After a period of two years, any discipline by the Board shall be suspended unless Respondent has violated this Agreed Order, or any Oklahoma Board of Pharmacy rule. This deferred penalty is intended to ensure continued compliance with the Oklahoma Board of Pharmacy rules.

5. Failure of Respondent to abide by any of the terms of this Agreed Order could result in disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

6. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

Kyle Whitehead, D.Ph., President
Oklahoma State Board of Pharmacy

State of Oklahoma)
) ss.
County of Oklahoma)

Subscribed and sworn before me on this the 13th day of June, 2018.



[SEAL]

Melissa Reichert
Notary Public

My Commission Expires: 3/13/22

Commission No: 18002597

I, Shaun Noorian, Founder and Chief Executive Officer, of Empower Pharmacy, have read the above Agreed Findings of Fact, Conclusions of Law and Agreed Order. I understand that by its terms Empower Pharmacy, will be waiving certain rights accorded under Oklahoma Law. I also understand that Empower Pharmacy, must comply with the terms and conditions of the Agreed Order or discipline will be imposed on Empower Pharmacy. On behalf of Empower Pharmacy, LLC., I agree to the above Agreed Order.

Dated this 11 day of June , 2018.

Shaun Noorian
Founder & Chief Executive Officer
Empower Pharmacy Respondent

State of Texas)
) ss.
County of Harris)

Subscribed and sworn before me on this the 11 day of June, 2018.

[SEAL]

SUSAN VAN BERGEN
Notary Public, State of Texas
Comm. Expires 02-10-2020
Notary ID 130533332

Notary Public

My Commission Expires: 02-10-2020

Commission No: 130533332

AGREED AND APPROVED:



Douglas A. Rice, OBA #16927
DERRYBERRY & NAIFEH, LLP
4800 North Lincoln Boulevard
Oklahoma City, OK 73105
Telephone: (405) 528-6569
Facsimile: (405) 528-6462
Attorney for Respondent

Notification of Stipulation and Consent Order for Informal Disposition

Empower Pharmacy entered into a Stipulation and Consent Order for Informal Disposition with the Idaho State Board of Pharmacy regarding allegations involving Empower Pharmacy's filling of prescriptions for three patients from an out-of-state prescriber that allegedly did not attain appropriate licensure from the Idaho Medical Board as defined in the Idaho Telehealth Access Act, and allegedly did not have the requisite prescriber-patient relationship prior to issuing a prescription.

In the attached Stipulation and Consent Order for Informal Disposition with Idaho, Empower did not admit or deny violating any law or the Board's rules. The Informal Disposition also does not constitute a restriction on Empower's pharmacy license, and, most importantly, the Informal Disposition is not considered discipline in Idaho. The Idaho State Board of Pharmacy also refrained from taking administrative or other action against Empower for the alleged conduct. Although the disposition with the Idaho State Board of Pharmacy is not considered discipline or a restriction on Empower's license we hereby inform you, out of an abundance of caution given diverse reporting requirements of state boards, of the attached Informal Disposition.

Please note, this Stipulation and Consent Order for Informal Disposition was included and communicated to The Nevada State Board of Pharmacy on 10/25/2019 regarding a new Out-of-State Pharmacy License application. The Board questioned Empower regarding this Stipulation and Consent Order for Informal Disposition during the Board's scheduled license approval meeting and had no concerns once explained, and our new Out-of-State Pharmacy License (PH04169) was approved on 12/16/2019.

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License of: EMPOWER PHARMACY, Mail Service Pharmacy License No. 36411MS, Respondent.	)	Case No. BOP 18-053 **STIPULATION AND CONSENT ORDER FOR INFORMAL DISPOSITION: I.C. § 67-5241(1) ("Stipulation")**

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that could constitute grounds for the initiation of an administrative case against Empower Pharmacy ("Respondent"); and,

WHEREAS, the Parties wish to expeditiously settle this matter of possible administrative violations relating to non-resident pharmacies dispensing controlled substances to Idaho residents, by Informal Disposition pursuant to Idaho Code § 67-5241(1);

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED between the undersigned Parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

2. Respondent is a licensee of the Board and holds Mail Service Pharmacy License No. 36411MS. Respondent's license is subject to the provisions of title 54, chapter 17, Idaho

Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

B. STIPULATED FACTS

1. Board staff's review of the PMP reports and records provided by Respondent revealed the following:

A. Idaho resident D.B. received from Respondent delivery of four (4) prescriptions fills for testosterone, a Schedule III controlled substance, which were issued in December 2016 through October 2017, by prescriber, J.S., located in Tampa, Florida.

B. Idaho resident J.S. received delivery of four (4) prescription fills for testosterone from Respondent, which were issued in October 2016 through September 2017 by prescriber, J.S., located in Tampa, Florida.

C. Idaho resident J.H. received delivery of six (6) prescription fills for testosterone from Respondent, which were issued in December 2016 through February 2018 by prescriber, J.S., located in Tampa, Florida.

2. Allegations arose from concerns of the Board that Respondent issued prescription drugs, including Schedule III controlled substances, to the above three (3) patients, based upon prescriptions which may have been invalid, the patients not having been seen in a face-to-face encounter by prescriber, J.S., in accordance with 21 U.S.C. § 829(e) prior to prescribing, and the prescriber not having been in compliance with the Idaho Telehealth Access Act, Title 54, Chapter 56, Idaho Code. Specifically, Idaho Code § 54-5703(4) requires telehealth providers to be licensed in the state of Idaho; Idaho Code § 54-5707(1) requires telehealth providers to have an established provider-patient relationship in order to issue prescription drug orders; and Idaho Code § 54-5705 requires two-way audio and visual interaction between the provider and patient.

In addition, 21 U.S.C. § 802(54) states that if telemedicine is being practiced, the patient must be in the presence of an onsite practitioner who possesses a valid DEA controlled substance registration and state license, and Idaho Code § 37-2716(a) requires the distant provider to hold a state controlled substance registration in the state where the patient is located.

3. Respondent asserts that the prescriber, J.S., advised Respondent that he had seen these three (3) patients in Florida, prior to prescribing for them, in accordance with 21 U.S.C. § 829(e).

4. Respondent admits that its business practices are subject to the following statutes and rules: Idaho Code §§ 54-1726(1)(f) and (2), 54-1728(1)(f) and (2), 37-2718(a)(4), 37-2719(c), 37-2722(c), 37-2723, 37-2730A(2), 37-2733(a)(1); and IDAPA 27.01.01.110 and 27.01.01.501.

5. Without Respondent admitting or denying that facts support a basis for discipline, and in lieu thereof, the Parties agree to an Informal Disposition pursuant to Idaho Code § 67-5241(1), as settlement and compromise, which shall not be deemed admitting to any acts or omissions which may be alleged, and Respondent agrees, the Board may enter its final Order as set forth in Section C below.

C. STIPULATED, AGREED SETTLEMENT

1. Respondent shall pay a monetary sum of fifteen thousand dollars ($15,000).

2. This monetary sum shall become payable after the Board approves and executes its Order approving this Settlement, to be paid to the Board within 180 days of the date the Order is executed.

3. Commencing the date the Stipulation is executed by the Board, Respondent shall verify that all prescribers issuing prescriptions to Idaho residents to be filled by Respondent shall

have the required prescriber licenses and controlled substance registrations which allow the prescribers to issue prescriptions to Idaho residents. Documentation of such verifications shall be retained by Respondent for two years from the date they are obtained and shall be provided to the Board upon its written request.

4. Further, Respondent shall designate a representative of its management to whom the Board may direct its communications and inquiries and who shall be responsible for responding to such inquiries. This representative shall be designated in writing within thirty (30) days of the date the Order incorporating this Stipulation is executed.

5. Failure to comply with any of the terms of this Stipulation may result in administrative action being taken against Respondent's mail service pharmacy license.

6. All costs associated with Respondent's compliance with the terms of this Stipulation shall be borne solely by Respondent. Nothing relating to this Stipulation shall be considered a restriction of Respondent's licensure.

D. COMPLIANCE WITH STIPULATION

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives its ability to challenge the Board's lack of authority of its Order upon appeal to a district court. Thereafter, if there shall be reason to believe Respondent may have violated any terms or conditions of this Stipulation, the Executive Director of the Board may file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondent that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing on such administrative complaint, any allegations of non-compliance may be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license may

then be subject to discipline, up to and including suspension or revocation. Accordingly, the Board retains jurisdiction over this proceeding, until all matters are finally resolved, as set forth in this Stipulation.

3. Any additional costs and/or attorney fees incurred by the Board in any future enforcement action based upon any allegation of this Stipulation shall be borne solely by Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondent, by signature of its authorized representative hereto, hereby acknowledges the following:

1. The Board has jurisdiction to proceed in this matter.

2. Respondent has read the above Stipulation fully and has had the opportunity to review it with legal counsel. Respondent understands and acknowledges that, by its terms, it is waiving certain rights provided under Idaho law.

3. Respondent acknowledges that, should the Board have brought a formal complaint in this matter, Respondent would have had certain rights, including but not limited to: the right to a full and complete hearing, pursuant to the Idaho Administrative Procedure Act; the right to confront and to cross examine witnesses; the right to present evidence, to call witnesses and to testify on its own behalf; the right to administrative reconsideration; the right to appeal any findings to the district court; and, any and other rights provided pursuant to the Idaho Administrative Procedure Act, statutes and rules governing the practice of pharmacy in Idaho, and otherwise as may be applicable pursuant to law. By entering into this Stipulation, Respondent agrees to forgo such rights and process and to waive same as part of the resolution of any allegations which may obtain.

4. Respondent understands that in signing this Stipulation, it agrees to the above terms without further process.

5. Respondent understands that, if approved as proposed, the Board shall execute and issue this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), according to the aforementioned terms, and Respondent agrees to the above Stipulation for settlement of all allegations, which allegations are contested and which Respondent denies. If the Board approves this Stipulation subject to changes, and those changes are acceptable to Respondent, Respondent acknowledges the Stipulation shall take effect, and an order modifying the terms of the Stipulation shall be issued. If the changes are unacceptable, or the Board rejects this Stipulation, this Stipulation shall be of no force or effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation shall not be admissible at any subsequent administrative hearing.

6. In the event this Stipulation is rejected by the Board, or any changes proposed by the Board are not accepted, Respondent waives any right it may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative proceedings, based on that the Board had considered and rejected this Stipulation.

7. Respondent understands the Board shall have the right to make full disclosure of this Stipulation to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. Respondent understands this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the Parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or

otherwise.

10. This Stipulation shall be presented by the Executive Director of the Board and the Deputy Attorney General responsible for this matter to the Board with a recommendation for approval at the next regularly scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective, until it has been approved by a majority of the Board, and a Board member signs the attached Order.

12. Each Party shall bear its own costs and fees associated with this matter.

DATED this 2nd day of July, 2019.

EMPOWER PHARMACY

By: _____

Printed: Shaun Noorian

Its: CEO

Authorized Representative for Respondent

I concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend that the Board adopt the same by its Order.

DATED this 3 day of July, 2019.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

STEVEN L. OLSEN
Deputy Attorney General

I also concur in this Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation") and recommend the Board adopt the same by its Order.

DATED this 9th day of July, 2019.

IDAHO BOARD OF PHARMACY

By: Nicole Chopski
Nicole Chopski, PharmD
Executive Director

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order for Informal Disposition: I.C. § 67-5241(1) ("Stipulation"), and it is hereby Ordered that the Parties shall comply with said terms and conditions.

DATED this 15 day of August, 2019.

Holly Henggeler, PharmD
Board Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of Aug, 2019, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER FOR INFORMAL DISPOSITION: I.C. § 67-5241(1) ("Stipulation") by the following method to:

Ms. Souchinda Nanthavongdouangay
Empower Pharmacy
5980 W. Sam Houston Pkwy N, Suite 300
Houston, TX 77041

- ☒ U.S. Mail
- ☐ Hand Delivery
- ☒ Certified Mail, Return Receipt Requested
- ☐ Overnight Mail
- ☐ Facsimile:

Steven L. Olsen
Deputy Attorney General
Civil Litigation Division
P. O. Box 83720
Boise, ID 83720-0010

- ☐ U.S. Mail
- ☐ Hand Delivery
- ☐ Overnight Mail
- ☐ Facsimile:
- ☒ Email: steven.olsen@ag.idaho.gov
  colleen.funk@ag.idaho.gov

Ellen Mitchell
Investigations Support Coordinator

16B

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Exela Pharma Sciences, LLC

Physical Address: 1245 Blowing Rock Blvd

City: Lenoir State: NC Zip Code: 28645

Telephone: 828-758-5474 Fax: 828-757-7888

Toll Free Number: 888-451-4321 (Required per NAC 639.708)

E-mail: info@exelapharma.com Website: www.exelapharma.com

Supervising Pharmacist: Bridget Wallace Archer (barcher@exela.us) Nevada License #: 20724

OK 10/31/2021

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY **Page 2**

FEI Number (From FDA application): 3008563008

Please provide the name of the facility as registered with the FDA and the registration number:
Exela Pharma Sciences, LLC 300856308

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Bridget Wallace Archer Nevada License Number: 20724

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

HANESH KONERU
Print Name of Authorized Person

11/2/2020
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY **Page 5**

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Exela PharmSci, Inc.

Address: 1245 Blowing Rock Blvd

City: Lenoir State: NC Zip: 28613

Telephone: 828-758-5474 Fax: 828-757-7888

Contact Person: Phanesh Koneru

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation? See attached Document.

a) _____
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information N/A.

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months. See attached Documents

List of officers and directors See attached Documents

Attachment A

Exela Pharma Sciences, LLC

Articles of Incorporation and Certificate of Corporate Status (Certificate of Good Standing)

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "EXELA PHARMA SCIENCES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF JANUARY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "EXELA PHARMA SCIENCES, LLC" WAS FORMED ON THE THIRTIETH DAY OF MAY, A.D. 2008.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4554331 8300

SR# 20210247163

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202384994

Date: 01-27-21

State of Delaware
Secretary of State
Division of Corporations
Delivered 08:29 AM 05/30/2008
FILED 08:20 AM 05/30/2008
SRV 080631761 - 4554331 FILE

CERTIFICATE OF FORMATION
OF
GALEXE PHARMA SCIENCES, LLC

The undersigned, an authorized natural person, for the purpose of forming a limited liability company, under the Delaware Limited Liability Company Act (6 Del. C. §18-101, et seq.), hereby certifies that:

1. The name of the limited liability company is Galexe Pharma Sciences, LLC.

2. The address of its registered office in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. The name of its Registered Agent at such address is Corporation Service Company.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this May 29, 2008.

/s/ Phanesh B. Koneru
Phanesh B. Koneru, Authorized Person

State of Delaware
Secretary of State
Division of Corporations
Delivered 03:21 PM 08/12/2009
FILED 02:55 PM 08/12/2009
SRV 090773994 - 4554331 FILE

CERTIFICATE OF AMENDMENT

TO THE

CERTIFICATE OF FORMATION

OF

GALEXE PHARMA SCIENCES, LLC

THE UNDERSIGNED, in accordance with Section 18-202 of the Delaware Limited Liability Company Act, 6 Del. C. § 18-101 *et seq.*, does hereby certify as follows:

1. The name of the limited liability company is "Galexe Pharma Sciences, LLC."

2. The Certificate of Formation of Galexe Pharma Sciences, LLC was filed with the Secretary of State of the State of Delaware on May 30, 2008.

3. Section 1 of the Certificate of Formation of Galexe Pharma Sciences, LLC is hereby amended and restated in its entirety to read as follows:

"The name of the limited liability company is Exela Pharma Sciences, LLC."

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment to the Certificate of Formation as of this 12th day of August, 2009.

By: _____
Name: Phanesh B. Koneru
Title: Authorized Person

Attachment B

Exela Pharma Sciences, LLC

Current Corporate Officer Information

Current LLC Corporate Officer Information

Exela Pharma Sciences, LLC
1245 Blowing Rock Boulevard
Lenoir, NC 28645

Phanesh Koneru, PhD, J.D., LL.M.
Title: Chief Executive Officer and President, Secretary
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Man of War Drive Waxhaw, NC 28173
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

SreeRama Murthy Mallipeddi, PhD
Title: Chief Science Officer
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Wexford Village Circle Lenoir, NC 28645
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

John Maloney, PhD
Title: Senior Vice President, Research and Development
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Mop Bucket Drive Salisbury, NC 28147
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

Mark T. Hartman
Title: Chief Commercial Officer
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Thronbury Place Waxhaw, NC 28173
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

Aruna Koganti, Ph.D., MBA
Title: Vice President of Clinical and Regulatory Affairs
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Waterfalls Road Lenoir, NC 28645
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

Gary Brennan
Vice President of Quality Assurance
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] Karla Circle Hendersonville, NC 28739
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

James Fife
Vice President of New Initiatives and Opportunities
Business: 1245 Blowing Rock Blvd. Lenoir, NC 28645
Home: [redacted] SW 95 Pl Gainesville, FL 32608
Business #: (828) 758-5474
Home #: [redacted]
SS#: [redacted]
DOB: [redacted]

Attachment C

Exela Pharma Sciences, LLC

Ownership Non Public Traded Corporation

Exela Pharma Sciences, LLC is 100 % owned by Exela PharmSci, Inc.

Employer Identification Number: 20-2848463

Attachment D

Exela Pharma Sciences, LLC

FDA Registration

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

EMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for **Exela**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Exela Pharma Sciences, LLC.	3008563008	831274399	ANALYSIS; LABEL; MANUFACTURE; PACK;	1245 Blowing Rock Blvd. 1325 William White Place 320 Cooperative Way 2101 Morganton Blvd, Lenoir, North Carolina (NC) 28645, United States (USA)	12/31/2021

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Wednesday, Oct 28, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Attachment F

Exela Pharma Sciences, LLC

North Carolina Department of Agriculture & Consumer Services Manufacturer License and Outsourcing Facility License

2021

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
764

LICENSE/CERTIFICATE: Manufacturer
TYPE: PRESCRIPTION DRUG LICENSE
Expiration Date: 12/31/2021

LICENSEE OR CERTIFICATOR:
EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd, 1325 William White Place NE,
320 Cooperative Way
Lenoir NC 28645

LICENSED 2021 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

2021

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
985

LICENSE/CERTIFICATE: Outsourcing Facility
TYPE:
Expiration Date: 12/31/2021

LICENSEE OR CERTIFICATOR:
EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd, 1325 William White Place NE,
320 Cooperative Way
Lenoir NC 28645

LICENSED 2021 NORTH CAROLINA

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Steven W. Troxler
STEVE TROXLER, COMMISSIONER

Attachment G

Exela Pharma Sciences, LLC

Online Verification of active licensure in good standing status from the North Carolina Department of Agriculture & Consumer Services for Manufacturer License and Outsourcing Facility License

Food & Drug Protection Division

Drug License Search

Go Back | New Search (search.asp)

Your search for Exela returned the following results...

EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd, 1325 William White Place NE,
320 Cooperative Way
Lenoir, NC 28645

License Type: **086**
License Number: **764**
Description: **Manufacturer**

Status: **Active – in good standing**
Issue Date: **12/16/2019**
Expiration Date: **12/31/2020**

EXELA PHARMA SCIENCES, LLC
1245 Blowing Rock Blvd, 1325 William White Place NE,
320 Cooperative Way
Lenoir, NC 28645

License Type: **093**
License Number: **985**
Description: **Outsourcing Facility**

Status: **Active – in good standing**
Issue Date: **12/16/2019**
Expiration Date: **12/31/2020**

EXELA PHARMA SCIENCES LLC
320 COOPERATIVE WAY
LENOIR, NC 28645

License Type: **093**
License Number: **1419**
Description: **Outsourcing Facility**

Status: **Inactive**
Issue Date:
Cancellation Date: **7/25/2019**

EXELA PHARMA SCIENCES LLC
320 COOPERATIVE WAY
LENOIR, NC 28645

License Type: **086**
License Number: **1341**
Description: **Manufacturer**

Status: **Inactive**
Issue Date: **3/18/2020**
Cancellation Date: **5/29/2020**

Attachment H

Exela Pharma Sciences, LLC

Email correspondence from the North Carolina Department of Agriculture & Consumer Services supporting online verification of status in good standing.

Reply all | Delete | Junk | Block | ...

FW: [External] Request for Assistance

JW

Jennifer Van Wyck
Mon 8/17/2020 1:08 PM
To: Bridget Archer

FYI

From: Redd, Shannon <Shannon.Redd@ncagr.gov>
Sent: Tuesday, June 16, 2020 10:54 AM
To: Jennifer Van Wyck <jvanwyck@exela.us>; Evans, Jeremy <Jeremy.Evans@ncagr.gov>
Subject: RE: [External] Request for Assistance

Good Morning Jennifer,

We do not complete license verification forms.

We have had no issues with any other state accepting our online verification in place of their verification form. You may visit our website for online verification:
http://www.ncagr.gov/aspzine/fd/fdpd/search.asp

Thanks,

Shannon B. Redd
Information Processing Tech
NCDA&CS
Food & Drug Protection Division
1070 Mail Service Center
Raleigh, NC 27699-1070
919-733-7366
919-733-6801 (Fax)
Shannon.Redd@ncagr.gov

got to be NC AGRICULTURE

From: Jennifer Van Wyck <jvanwyck@exela.us>
Sent: Tuesday, June 16, 2020 10:48 AM
To: Evans, Jeremy <Jeremy.Evans@ncagr.gov>
Cc: Redd, Shannon <Shannon.Redd@ncagr.gov>
Subject: [External] Request for Assistance

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Jeremy,

17

May 24, 2021

Nevada State Board of Pharmacy

Attn: Licensing Department

985 Damonte Ranch Pkwy, Ste 206

Reno, NV 89521

Re: Phamacy licenses IB03806 and IB03728

Good evening,

We are writing in regards to NRS 639.220 3. (a) which states that a person may not act as managing pharmacist for more than one licensed pharmacy. A waiver may be granted by the Board to the mananging pharmacist of a pharmacy located in a hospital with fewer than 100 beds.

We are requesting a waiver to allow Kodilichi Izuora (license #18081) the ability to manage 2 hospitals – Dignity – St. Rose Dominican North Las Vegas Campus (license # IB03806) and Dignity – St. Rose Domincian Flamingo Campus (license # IB03728). Change in managing pharmacist forms were submitted to the Board on 03/24/21. Previously, a waiver was granted allowing our former managing pharmacist, Emmanuel Ebo (license #07325), the ability to manage our 4 hospistals. Each hospital has 8 licensed inpatient beds, meeting the fewer than 100 bed requirement for the waiver.

Thank you very much for your assistance and please let us know if you have any questions.

Sincerely,

Tamarah S. Walker, PharmD (license #19318)

System Director, Pharmacy

Emerus Holdings, Inc

[redacted]

Kodilichi Izuora, PharmD

Managing Pharmacist

PHARMACY MANAGER'S RESPONSIBILITIES

(PHARMACY MANAGER, MUST READ, SIGN AND DATE THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220).

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282; NAC 639.510; NAC 639.473(2).

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NRS 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254(2)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11; NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from the last fill date for original paper prescription). (NRS 639.236; NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268; NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286; NAC 639.487)

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

KCAC — 3/17/21

Signature of New Managing Pharmacist (no stamps or copies) — Date

Board Use Only
Date Received:_____ Amount: 50

MD # 20970130097 4

Posted 6/30/2011

NEVADA STATE BOARD OF PHARMACY

985 DAMONTE RANCH PKWY, SUITE 206 – RENO, NV 89521 - (775) 850-1440

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

CHANGE OF MANAGING PHARMACIST FORM

Registration Fee: $50.00

(non-refundable money order or cashier's check only, no cash or business check's)

*This form is only required for pharmacies physically located in Nevada. We only require written notification from an out-of-state pharmacy for a manager change.

General Information

**Nevada Pharmacy Board License #: IB03706
**(Do not use your RPH, NPI or DEA number. Number begins with a PH, IA, IB)

Pharmacy Name: DIGNITY HEALTH- ST ROSE DOMINICAN NORTH LAS VEGAS Store #: _____

Address: 1550 W. CRAIG RD

City: NORTH LAS VEGAS State: * NV Zip: 80932

Telephone: 702-777-3615 Fax: 702-642-0808

New Managing Pharmacist Name: _____

License #: 18081 Date Started: 3/17/21

Pharmacy email: kodi.izuora@emerus.com

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?....	☐	☑
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?.....	☐	☑
2. Been the subject of an administrative action whether completed or pending in any state?	☐	☑
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.....	☐	☑

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide documentation:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court

18

NEVADA STATE BOARD OF PHARMACY

985 DAMONTE RANCH PKWY, SUITE 206 – RENO, NV 89521 - (775) 850-1440

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

CHANGE OF MANAGING PHARMACIST FORM

Registration Fee: $50.00

(non-refundable money order or cashier's check only, no cash or business check's)

*This form is only required for pharmacies physically located in Nevada. We only require written notification from an out-of-state pharmacy for a manager change.

General Information

**Nevada Pharmacy Board License #: PHC02018
**(Do not use your RPH, NPI or DEA number. Number begins with a PH, IA, IB)

Pharmacy Name: PharMerica Reno Store #: 7015

Address: 4690 Longley Ln Suite A-39

City: Reno State: * NV Zip: 89502

Telephone: 775-825-6117 Fax: 877-262-0502

New Managing Pharmacist Name: Daniel Francke

License #: 20046 Date Started: 11/11/20

Pharmacy email: daniel.francke@pharmerica.com

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?....	☐	☒
1. Been charged, arrested or convicted of a felony or misdemeanor in any state?.....	☒	☐
2. Been the subject of an administrative action whether completed or pending in any state?	☐	☒
3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?.....	☐	☒

If you marked **YES** to any of the numbered questions (**1-3**) above, include the following information & **provide documentation**:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
	CA	3/17/20	TM20-000040	Nevada	Truckee, CA

PHARMACY MANAGER'S RESPONSIBILITIES

(PHARMACY MANAGER, MUST READ, SIGN AND DATE THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220).
2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282; NAC 639.510; NAC 639.473(2).
3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NRS 639.540)
4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC639.254(2)
5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11; NAC 453.475)
6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)
7. Maintain prescription records/logs for 2 years (2 years from the last fill date for original paper prescription). (NRS 639.236; NAC 453.480)
8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268; NAC 453.485)
9. Maintain invoice records separated as required for 2 years. (NRS 454.286; NAC 639.487)

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

Signature of New Managing Pharmacist (no stamps or copies) — Date: 11/11/20

Board Use Only
Date Received:_____ Amount: 50.00

Check #1019444400

Posted 6/30/2011

TM20-000040 PEOPLE VS FRANCKE, DANIEL REED

- Case Type:
  TRUCKEE CRIMINAL MISD
- Case Status:
  CLOSED
- File Date:
  02/13/2020
- DCM Track:
- Action:
  Driving Under the Influence of Alcohol or Drugs
- Status Date:
  02/13/2020
- Case Judge:
- Next Event:

All Information | Party | Charge | Ticket/Citation # | Event | Docket | Financial | Receipt | Financial Dockets | Disposition

Party Information

FRANCKE, DANIEL REED
- DEFENDANT

- DOB
  xx/xx/1985
- DOD
- Disposition
- Disp Date

Alias

Party Attorney

More Party Information

UNKNOWN
- OFFICER

- DOB
- DOD
- Disposition
- Disp Date

Alias

Party Attorney

More Party Information

Party Charge Information

- **FRANCKE, DANIEL REED**
- - DEFENDANT
  Charge # 1 :
  VC23152(a) - MISD C Driving Under the Influence of Alcohol or Drugs
- Original Charge

- VC23152(a) Driving Under the Influence of Alcohol or Drugs (MISD C)
- Indicted Charge
- Amended Charge
- DV Related?
- Modifiers
- Stage Date

- Ticket #
- ATN #
- Tracking #
- Place of Offense
- COUNTY OF NEVADA
- Date of Offense
- 12/08/2019
- Complainant

Party Charge Disposition
Disposition Date
Disposition
03/17/2020
DISMISSED

Sentencing Information

- **FRANCKE, DANIEL REED**
- - DEFENDANT

Charge # 2 :
VC23152(b) - MISD C Driving While Having a 0.08% or Higher Blood Alcoh

- Original Charge
- VC23152(b) Driving While Having a 0.08% or Higher Blood Alcoh (MISD C)
- Indicted Charge
- Amended Charge
- DV Related?
- Modifiers
- Stage Date

- Ticket #
- ATN #
- Tracking #
- Place of Offense
- COUNTY OF NEVADA
- Date of Offense
- 12/08/2019
- Complainant

Party Charge Disposition
Disposition Date
Disposition
03/17/2020
DISMISSED

Sentencing Information

- **FRANCKE, DANIEL REED**
- - DEFENDANT

Charge # 3 :
VC23103(23103.5) - MISD C WET/RECKLESS

- Original Charge
- VC23103(23103.5) WET/RECKLESS (MISD C)
- Indicted Charge
- Amended Charge

- DV Related?
- Modifiers
- Stage Date

- Ticket #
- ATN #
- Tracking #
- Place of Offense
- COUNTY OF NEVADA
- Date of Offense
- 12/08/2019
- Complainant

Party Charge Disposition
Disposition Date
Disposition
03/17/2020
NOLO CONTENDRE PLEA

Sentencing Information

Ticket/Citation

Citation # : - COUNTY OF NEVADA
- **Offense Date**
- **12/08/2019**

- Agency
- CA HIGHWAY PATROL
- Officer
- UNKNOWN(000)
- Second Officer
- Complainant

- Speed Cited
- Speed Limit
- Location
- Insured/Proof
- Accident
- N
- Work Zone
- Haz Mat
- Points
- 2
- Priors
- License Taken
- N

- State
- Year
- Type
- Style
- Color

Events

Date/Time	Location	Type	Result	Event Judge
03/16/2020 09:00 AM	Truckee - Dept A - Main Courtroom	TRUCKEE ARRAIGNMENT	CONTINUED	TAMIETTI, ROBERT L

Date/Time	Location	Type	Result	Event Judge
03/17/2020 08:31 AM	Truckee - Dept A - Main Courtroom	TRUCKEE ARRAIGNMENT	NO CONTEST PLEA ENTERED	TAMIETTI, ROBERT L
04/07/2020 08:30 AM	Truckee - Dept A - Main Courtroom	MISCELLANEOUS REVIEW	VACATED	TAMIETTI, ROBERT L
05/18/2020 08:30 AM	Truckee - Dept A - Main Courtroom	PROOF OF ENROLLMENT	VACATED	TAMIETTI, ROBERT L

Docket Information

Date	Description	*Docket Text*	Amount Owed
01/13/2020	MISDEMEANOR COMPLAINT	MISDEMEANOR COMPLAINT	
01/13/2020	BAIL SET:	BAIL SET: Arrest Bond Added to Case with: Action Code: Driving Under the Influence of Alcohol or Drugs Arrest Date: 12/08/2019 Bond Status: O.R. RELEASE Status Date: 03/16/2020 Blanket Bond: No Okay to Apply: No	
01/13/2020	HEARING SET:	HEARING SET: Event: TRUCKEE ARRAIGNMENT Date: 03/16/2020 Time: 9:00 am Judge: TAMIETTI, ROBERT L Location: Truckee - Dept A - Main Courtroom Result: CONTINUED	
03/17/2020	HEARING SET:	HEARING SET: Event: TRUCKEE ARRAIGNMENT Date: 03/17/2020 Time: 8:31 am Judge: TAMIETTI, ROBERT L Location: Truckee - Dept A - Main Courtroom Result: NO CONTEST PLEA ENTERED	
03/17/2020	HEARING CONTINUED	HEARING CONTINUED The following event: TRUCKEE ARRAIGNMENT scheduled for 03/16/2020 at 9:00 am has been resulted as follows: Result: CONTINUED Judge: TAMIETTI, ROBERT L Location: Truckee - Dept A - Main Courtroom	
03/17/2020	HEARING SET:	HEARING SET: The following event: TRUCKEE ARRAIGNMENT scheduled for 03/17/2020 at 8:31 am has been rescheduled as follows: Event: PROOF OF ENROLLMENT Date: 04/07/2020 Time: 8:30 am Judge: TAMIETTI, ROBERT L Location: Truckee - Dept A - Main Courtroom	
03/17/2020	HEARING SET:	HEARING SET: Event: PROOF OF ENROLLMENT Date: 05/18/2020 Time: 8:30 am Judge: TAMIETTI, ROBERT L Location: Truckee - Dept A - Main Courtroom	

Date	Description	*Docket Text*	Amount Owed
		Result: VACATED	
03/17/2020	EMERGENCY MEDICAL AIR TRANSPORT PENALTY (GC 76000.10)	COUNTY PENALTY - EMERGENCY MEDICAL AIR TRANSPORTATION (GC 76000.10) Charge #3: WET/RECKLESS Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195486 Date: 04/07/2020	$4.00
03/17/2020	INSTALLMENT PAYMENT FEE PC1205(E)	INSTALLMENT PAYMENT FEE PC1205(E) Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195088 Date: 03/30/2020	$25.00
03/17/2020	BAIL SET:	BAIL SET: Arrest Bond Added to Case with: Action Code: WET/RECKLESS Arrest Date: 03/17/2020 Bond Status: SENTENCED DEFENDANT Status Date: 03/17/2020 Blanket Bond: No Okay to Apply: No	
03/17/2020	PLEA GUILTY/NOLO	PLEA GUILTY/NOLO Case disposed with disposition of PLEA GUILTY/NOLO on 03/23/2020.	
03/17/2020	CHARGE DISMISSED	CHARGE DISMISSED Charge(s) 1 disposed with a disposition of CHARGE DISMISSED Charge #1: Driving Under the Influence of Alcohol or Drugs	
03/17/2020	CHARGE DISMISSED	CHARGE DISMISSED Charge(s) 2 disposed with a disposition of CHARGE DISMISSED Charge #2: Driving While Having a 0.08% or Higher Blood Alcohol	
03/23/2020	COURT OPERATIONS FEE - CRIMINAL/TRAFFIC - PC 1465.8	COURT OPERATIONS FEE - CRIMINAL/TRAFFIC - PC 1465.8 Charge #3: WET/RECKLESS Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195486 Date: 04/07/2020	$40.00
03/23/2020	MISDEMEANOR/FELONY CONVICTION ASSESSMENT (GC 70373)	MISDEMEANOR/FELONY CONVICTION ASSESSMENT (GC 70373) Charge #3: WET/RECKLESS Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195088 Date: 03/30/2020	$30.00
03/23/2020	RESTITUTION FUND FINE - MISD PC 1202.4	RESTITUTION FUND FINE - MISD PC 1202.4 Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195088 Date: 03/30/2020 Receipt: 195486 Date: 04/07/2020	$150.00
03/23/2020	BLOOD DRAW FEE - PC 1463.14(b)	BLOOD DRAW FEE - PC 1463.14(b) Receipt: 194862 Date: 03/23/2020 Receipt 194862 reversed by 195087 on 03/30/2020. Receipt: 195088 Date: 03/30/2020	$50.00
03/23/2020	DMV - ABSTRACT ISSUED	DMV - ABSTRACT ISSUED	

Date	Description	*Docket Text*	Amount Owed

Financial Summary

Cost Type	Amount Owed	Amount Paid	Amount Adjusted	Amount Outstanding
COST	$295.00	$295.00	$0.00	$0.00
FEES (OTHER REIMBURSABLE COSTS)	$4.00	$4.00	$0.00	$0.00
Total	Total $299.00	Total $299.00	Total $0.00	Total $0.00

Receipts

Receipt Number	Receipt Date	Received From	Payment Amount
194862	03/23/2020	FRANCKE, DANIEL REED	$299.00
195087	03/30/2020	FRANCKE, DANIEL REED	-$299.00
195088	03/30/2020	FRANCKE, DANIEL REED	$200.00
195486	04/07/2020	Daniel Francke	$99.00
Total	Total	Total	Total $299.00

Financial Docket Information

Date	Description	Owed	Adjusted	Paid	Due	Due Date
01/13/2020	MISDEMEANOR COMPLAINT	$0.00	$0.00	$0.00	$0.00	
01/13/2020	BAIL SET:	$0.00	$0.00	$0.00	$0.00	
01/13/2020	HEARING SET:	$0.00	$0.00	$0.00	$0.00	
01/13/2020	DISTRICT ATTORNEY MISDEMEANOR OFFER SHEET	$0.00	$0.00	$0.00	$0.00	
03/17/2020	HEARING SET:	$0.00	$0.00	$0.00	$0.00	
03/17/2020	HEARING CONTINUED	$0.00	$0.00	$0.00	$0.00	
03/17/2020	HEARING RESULTED:	$0.00	$0.00	$0.00	$0.00	
03/17/2020	HEARING SET:	$0.00	$0.00	$0.00	$0.00	
03/17/2020	HEARING SET:	$0.00	$0.00	$0.00	$0.00	
03/17/2020	MINUTES - SENTENCE	$0.00	$0.00	$0.00	$0.00	
03/17/2020	EMERGENCY MEDICAL AIR TRANSPORT PENALTY (GC 76000.10)	$4.00	$0.00	$4.00	$0.00	
03/17/2020	INSTALLMENT PAYMENT FEE PC1205(E)	$25.00	$0.00	$25.00	$0.00	
03/17/2020	BAIL SET:	$0.00	$0.00	$0.00	$0.00	
03/17/2020	PLEA GUILTY/NOLO	$0.00	$0.00	$0.00	$0.00	
03/17/2020	CHARGE DISMISSED	$0.00	$0.00	$0.00	$0.00	
Total	Total	Total $299.00	Total $0.00	Total $299.00	Total $0.00	Total

Date	Description	Owed	Adjusted	Paid	Due	Due Date
03/17/2020	CHARGE DISMISSED	$0.00	$0.00	$0.00	$0.00	
03/23/2020	COURT OPERATIONS FEE - CRIMINAL/TRAFFIC - PC 1465.8	$40.00	$0.00	$40.00	$0.00	
03/23/2020	MISDEMEANOR/FELONY CONVICTION ASSESSMENT (GC 70373)	$30.00	$0.00	$30.00	$0.00	
03/23/2020	RESTITUTION FUND FINE - MISD PC 1202.4	$150.00	$0.00	$150.00	$0.00	
03/23/2020	BLOOD DRAW FEE - PC 1463.14(b)	$50.00	$0.00	$50.00	$0.00	
03/23/2020	8715: ORIGINAL	$0.00	$0.00	$0.00	$0.00	
03/23/2020	DMV - ABSTRACT ISSUED	$0.00	$0.00	$0.00	$0.00	
03/26/2020	HEARING RESULTED:	$0.00	$0.00	$0.00	$0.00	
04/02/2020	HEARING RESULTED:	$0.00	$0.00	$0.00	$0.00	
04/02/2020	PROOF OF COMPLETION - FIRST OFFENDER PROGRAM	$0.00	$0.00	$0.00	$0.00	
Total	Total	Total $299.00	Total $0.00	Total $299.00	Total $0.00	Total

Case Disposition

Disposition	Date	Case Judge
PLEA GUILTY/NOLO	03/17/2020	

2831

Nevada State Board of Pharmacy

For licensing inquires please send an email to, pharmacy@pharmacy.nv.gov (mailto:pharmacy@pharmacy.nv.gov).

For current information on disciplinary actions taken against licensees, please send an email to shunting@pharmacy.nv.gov (mailto:shunting@pharmacy.nv.gov).

VERIFY LICENSE

Last Name	First Name	License#	City	State	Country	Discipline	Action
FRANCKE	DANIEL	20066	TRUCKEE	CA	United States	None	

License Number : 20066

Name : FRANCKE, DANIEL

License Type : Pharmacist

License Status : Active

License Date : 12/06/2018

Discipline :

Expiration Date : 10/31/2021



Copyright © 2018 | Nevada State Board of Pharmacy (http://bop.nv.gov/) | All Rights Reserved

19

Dear Nevada State Board of Pharmacy Members,

I am submitting this letter of request to provide medication consultation services to patients suffering from nausea and vomiting in pregnancy, ranging from Morning Sickness to Hyperemesis Gravidarum (HG).

As a pharmacist educated in safe use of medications during pregnancy, certified in interpreting pharmacogenetic test results, and a board member of the HER Foundation thoroughly trained in our clinical resources (www.hyperemesis.org), I would like to offer education, personalized medication recommendations and patient advocacy to the pregnant women reaching out to me for help.

Without any FDA approved medications for HG and symptoms often dismissed by providers, patients are left to suffer on their own, relying on repeated visits to emergency rooms for rehydration at a cost of over $2.5 billion annually. HG is a leading cause of hospital admissions due to pregnancy, and consequences from untreated HG are vast including preeclampsia, preterm labor and premature birth. There are also profound mental health implications from isolation and months of malnutrition. Many women lose their jobs and then terminate out of desperation. Tragically, some lose their lives and that of their baby(ies) when left untreated, contributing to the increasing rate of maternal mortality in the United States. Much of these complications are preventable with proper support, nutrition and medication.

Following are the details required per NAC 639.403 sections (a) through (k) to request permission to offer medication consultations outside of a traditional pharmacy:

a. Name of pharmacist: Danielle Plummer, PharmD

b. Description of the services pharmacist intends to provide at the site:
   i. Patient education on disease state and treatment options
   ii. Practitioner education on disease state and treatment options
   iii. Pharmacogenetic Consultations
   iv. Personalized medication and nutrition recommendations
   v. Patient advocacy to enhance communication between patients, providers and family members

   Services will be provided to women suffering from Morning Sickness and Hyperemesis Gravidarum. Initial patient assessments include a full health history (allergies, medications, vaccines and pertinent lab results), details on current and past pregnancies, a HELP (HyperEmesis Level Prediction) score assessment to determine severity of disease, discussion on patient's pregnancy desires and goals to reach the desired state. A plan of care will then be created based on the HER Foundation Treatment Algorithm, pharmacogenetic test results (if completed) and availability of medications available on the patient's insurance formulary along with financial considerations. Private consultations are completed one to two times weekly based on need, and group support is available daily. Education will be provided as to when to go to the emergency room for IV therapy and how to advocate for necessary therapy. Educational materials, printed or electronic, for patients as well as practitioners will be distributed as needed.

   Two options for services are available:

   1. A six-week education and support program
   2. Medication education and recommendations as needs change throughout the pregnancy

   Goals include: decreasing the persistent feeling of being helpless, increasing nutrition to prevent complications, understanding steps to be be taken seriously by medical providers, eliminating fear of medications causing birth defects, having support of your loved ones, returning to work

c. The location at which the pharmacist will provide the services:

   All telehealth visits will happen at my office: 9064 Dove River Rd. Las Vegas, NV 89134

(d) An identification of the types of patients or other persons to whom the pharmacist intends to provide the services:
Pregnant women with severe nausea and vomiting.

(e) An identification of the types of pharmacies or other entities to whom the pharmacist intends to provide the services:
HG Clinical Solutions partners with the HER Foundation to provide medication education.

(f) A description of all resources, both paper and electronic, that will be available to the pharmacist in the course of providing the services;
All patient records are kept in a HIPAA compliant EHR called DocStation. Resources available to the pharmacist include Medscape, Epocrates, GlobalRPh, Pharmacist's Letter, Her Foundation Clinical Tools (www.hyperemesis.org/tools) and other evidence-based sources.

(g) The days and hours during which the pharmacist intends to provide the services;
Consultations are by appointment only. Live group support sessions will be provided online twice per week. Day and time of sessions are to-be-determined. Patient advocacy will be offered remotely based on the patient's needs.

(h) An explanation of the policy of the pharmacist for users of the services when the pharmacist is unavailable;
Private consultations are by appointment only. Patients can have questions answered daily through a private online support group. Patients are instructed to call their primary care doctor or use emergency services when necessary.

(i) An explanation of the policy of the pharmacist regarding the confidentiality and security of the patient data that will be gathered, made and maintained as part of the services which are provided, including, without limitation, paper and electronic records;
All patient records are kept in a HIPAA compliant EHR called DocStation.

(j) Whether the services provided will be affiliated with, an adjunct of or otherwise related to a licensed pharmacy; and
Services provided will not be affiliated with a licensed pharmacy.

(k) A description of the business plan for the services provided:

Executive Summary
HG Clinical Solutions provides consultation services to pregnant women suffering from extreme nausea and vomiting. Services include educating patients on treatment options, pharmacogenetic testing, personalized medication and nutrition recommendations, practitioner education, and patient advocacy to enhance communication between patient and providers.

Mission Statement
To provide information to pregnant women to decrease their nausea and vomiting therefore improving their quality of life without added stress by understanding treatment options and educating friends, family and medical providers.

Principal Member
Danielle Plummer, PharmD, Owner, Primary consultant

Legal Structure
HG Clinical Solutions is a DBA under Danielle Raiman Plummer LLC

Market Research
HG is "a potentially life-threatening pregnancy disease that may cause weight loss, malnutrition, dehydration, and debility due to severe nausea and/or vomiting, and may cause long-term health issues for mother and baby(ies)." Complications from the chronic dehydration and malnutrition caused by HG are vast and when not treated properly can be fatal for mom and/or baby. Hundreds of thousands of women who are suffering from this debilitating disease often have their symptoms dismissed by the medical community. While women wait to see their obstetrician or midwife, medical help is sought at emergency rooms whose practitioners are not trained in treating HG. There is a

great need to educate providers on the seriousness of the disease state and what treatment options are available. Women from all around the world are desperate for treatment options and to be taken seriously by the medical community.

Description of Customers
Pregnant women with debilitating nausea and vomiting whose symptoms are not improving through treatments prescribed by their medical providers. Characteristics of these women include inability to complete tasks of daily living, job loss due to inability to work, vomiting every time they eat or drink, have doctors who make them feel shameful for asking for help, are unable to care for other children, have friends and family who do not understand or think they are exaggerating, scared to take medications due to risk of birth defects, have spent weeks vomiting crackers and ginger, are anxious about the remaining months of this pregnancy and are suffering from isolation and depression.

Company Advantages

- Founded by a Doctor of Pharmacy and three time survivor of Hyperemesis Gravidarum
- Clients are treated with the care of a doula who has the knowledge of a retail and hospital pharmacist
- Well respected by women around the world for knowledge of medications used in HG patients
- Many years of experience training MDs, NPs and PAs in necessary treatments both inpatient and outpatient
- Virtual company without many overhead costs
- Supported by the HER Foundation, the world's leading expert in HG education and advocacy

Services
Services include:

- Educational information on stepwise medication options for both inpatient and outpatient treatments
- Comprehensive personalized medication recommendations to include both prescription and over the counter options using the following strategies:
    - Pharmacogenetic testing
    - Financial considerations
    - Consecutive visits will address compliance and patient concerns
    - Determining best medication delivery options other than oral and location to receive the medications: IV and topical routes from home health services, infusion centers, compounded medications.
- Practitioner education both inpatient and outpatient
- Patient advocacy to:
    - Enhance communication and coordinate care between patient and providers
    - Resolve gaps in care
        - First trimester: Pregnant women do not see their obstetrician or midwife until around 10 weeks, leaving them untreated during the most important time for optimal nutrition
        - Hospital discharge: HG women are often discharged from the hospital without proper diagnosis of their disease or prescriptions to hold them over until they see their obstetrician or midwife
    - Increase disease state understand of friends and family so patient feels supported and isolation is limited
    - Ensure proper documentation from providers to be given to employer for disability or FMLA

Marketing
HG Clinical Solutions markets through the following channels:

- Facebook through group pages and live events
- Instagram through live events
- Recommendations and referrals from current clients and medical practices
- Email list
- www.HGPharmacist.com landing page from Google SEO

Thank you very much for your consideration.

Sincerely,

Danielle Plummer, PharmD
Nevada Pharmacist License #19380
HG Clinical Solutions
Office: (702) 800-0930
[redacted]
Email: info@hgpharmacist.com

20

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

Y

APPLICATION BY EXAMINATION AS A PHARMACIST

If you are requesting examination eligibility for initial licensure and/or you don't meet the requirements for reciprocation.

Total Fee: $250.00 (Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)

Made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: ADAM Middle: PAUL Last: KATSCHKE

Mailing Address: [redacted]

City: CALIENTE State: NV Zip Code: 89008

Telephone: [redacted] E-mail Address: [redacted]

Date of Birth: [redacted] Place of Birth: Fredericksburg, VA

SS# or ITIN: [redacted] Sex: ☐ M or ☒ F

(Full Number Required)

College of Pharmacy Information

Graduation Date: 05/14/2000 (mm/dd/yy)

Degree Received: ☒ PharmD ☐ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: Creighton University

Location of School: Omaha, NE

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information

Board Use Only

Processed: _____ Amount: 250 Entity #: _____

Email _____ NAPLEX _____ MPJE _____

Other states where you are (or were) licensed as a pharmacist or print "none"

State	Lic#	Is the license Active?	State	Lic #	Is the License Active?
NV	15601	Yes ☐ No ☒			Yes ☐ No ☐
UT	4762546-1701	Yes ☐ No ☒			Yes ☐ No ☐

**Attach separate sheet if needed

Have you ever served in the military, either active, reserve or retired? Yes ☒ No ☐

Branch: Public Health Service
Military Occupation/Specialty: Pharmacy Intern
Dates of Service: 5/1998 - 9/1998

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: N/A

	Yes	No
1. Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
2. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
3. Been the subject of a board citation or an administrative action or board citation whether completed or pending in any state	☒	☐
4. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☒	☐

If you marked **YES** to any of the numbered questions (**1-3**) above, include the following information & **provide an explanation and/or documentation**:

Board Administrative Action:	State	Date:	Case #:
Licenses surrendered	NV UT	10 16 2016 12/31/2016	

Criminal Action:	State	Date:	Case #:	County	Court
	NV	1/13/2017	CR-0717016	Lincoln	Seventh Judicial District Court

FEDERALLY MANDATED REQUIREMENTS

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications.

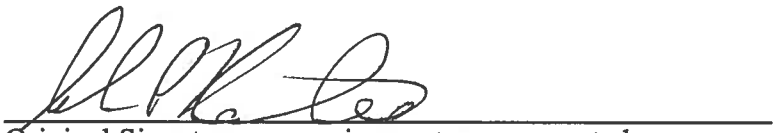
4. Are you the subject of a court order for the support of a child?.....Yes ☐ No ☒
4a. If you marked Yes, to the question 4, are you in compliance with the court order?.....Yes ☐ No ☐

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, its members, servants or employees because or by reason of the use of the authorization.

I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices.

I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.



Original Signature, no copies or stamps accepted

3/30/2021

Date

FILED
OCT 12 2016
NEVADA STATE BOARD
OF PHARMACY

1

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	)	**CASE NO. 15-017-RPH-S**
	)	
Petitioner,	)	**VOLUNTARY SURRENDER OF**
v.	)	**REGISTRATION/CERTIFICATE IN**
	)	**LIEU OF OTHER DISCIPLINARY**
ADAM KATSCHKE, RPH	)	**ACTION**
Certificate of Registration No. 15601,	)	
	)	
Respondent.	/	

I, ADAM P. KATSCHKE, R.Ph., acting by and through my counsel, Daniel Albregts, Esq., wish to voluntarily surrender my Nevada Pharmacist License, Certificate of Registration No. 15601, in lieu of other possible administrative discipline. To that end, I voluntarily and knowingly admit as follows:

1. I am registered as a pharmacist in the State of Nevada, and I was so registered at the time of the conduct described in the *Notice of Intended Action and Accusation* ("Accusation") on file in the above captioned matter, and as summarized herein, and I am, therefore, subject to the jurisdiction of the Nevada State Board of Pharmacy ("Board").

2. That on or about September 9, 2016, the Board filed the Accusation, pursuant to NRS 639.233B.127(3) and NRS 639.241, alleging six causes of action against me, each relating to the unlawful possession, diversion, or dispensing of controlled substances and/or dangerous drugs, or to fraudulent acts relating to controlled substances and/or dangerous drugs.

3. I admit that if this matter had proceeded to a hearing, Board Staff, through its counsel, may have presented evidence, through the testimony of witnesses and through the admission of documentary evidence, sufficient to prove the allegations in the Accusation.

4. Rather than spend the time and incur the potential costs associated with such a hearing, and in lieu of other possible disciplinary action by the Board, I choose to voluntarily surrender my Nevada pharmacist license.

5. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the First Cause of Action. The alleged conduct constitutes a violation NRS 454.311 ("[a] person who knowingly . . . [f]ills a prescription which is not genuine . . . is guilty of a category E felony . . . .") and NRS 454.221(1) (it is unlawful to "furnish[*sic*] any dangerous drug [to another person] . . . unless the dangerous drug was obtained originally by a legal prescription.") Those violations are grounds for discipline, including suspension or revocation of a pharmacist license, per NRS 639.210(7).

6. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the Second Cause of Action. That conduct constitutes a violation of NRS 453.331(1)(b) ("[i]t is unlawful for a person knowingly or intentionally to . . . . [u]se in the course of the manufacture or distribution of a controlled substance a registration number which is . . . issued to another person") and NRS 453.331(1)(f) (it is "unlawful for a person to knowingly or intentionally . . . [s]ign the name of . . . another person on any prescription for a controlled substance or falsely make, alter, forge, utter, publish or pass, as genuine, any prescription for a controlled substance.") Those violations constitute felonies (NRS 453.331(2)), and are thus grounds on which the Board may revoke or suspend any license or registration it issued.

7. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the Third Cause of Action. That conduct constitutes violations of NRS 639.210(1), (4) and (12), and is therefore grounds on which the Board may revoke or suspend any license or registration it issued.

8. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the Fourth Cause of Action. I pleaded guilty to

Insurance Fraud, a category D felony in violation of NRS 686A.2815, and to Submitting False Claims: Medicaid Fraud, a category D felony in violation of NRS 422.540, in a criminal action (Case No. CR071016). That plea constitutes the conviction of a felony relating to a license issued pursuant to NRS Chapter 639, or other crime involving moral turpitude, dishonesty or corruption. (*See* NRS 639.006.) That conviction is grounds on which the Board may revoke or suspend any license or registration it issued. *See* NRS 639.210(7).

9. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the Fifth Cause of Action. I pleaded guilty to Submitting False Claims: Medicaid Fraud, a category D felony in violation of NRS 422.540, in a criminal action (Case No. CR071016). That conduct—submitting charges and claims that are false to the State and its political subdivisions, namely Medicaid—constitutes the violation of NRS 639.2815 as well. That conduct is therefore grounds for discipline against my pharmacist license pursuant NRS 639.210, up to, and including, suspension or revocation of that license.

10. I admit the factual allegations in the Accusation, if proven at a hearing, would constitute grounds for discipline as alleged in the Sixth Cause of Action. As the owner and managing pharmacist of Meadow Valley Pharmacy, I knowingly allowed violations of Nevada State Law as alleged in the Accusation. Those violations are grounds for discipline against my pharmacist license pursuant to NRS 639.210(15), up to, and including, suspension or revocation of that license.

11. As a result of the forgoing, I agree to sell my entire interest in Meadow Valley Pharmacy and its associated remote pharmacy, Pahrangat Valley Pharmacy, according to the requirements set forth in paragraphs 17 through 20 of the *Voluntary Surrender of Registration/Certificate in Lieu of other Disciplinary Action* I entered into with the Board simultaneously with the instant agreement.

12. I agree to pay an administrative fee of ten thousand dollars ($10,000.00) to partially offset the Board's investigative and administrative costs associated with investigating

and prosecuting this action. I agree to pay that administrative fee by *cashier's check* or *certified check* or *money order* made payable to "Nevada State Board of Pharmacy," to be received by the Board's Reno office located at 431 W. Plumb Lane, Reno, Nevada 89509, within thirty (30) days of the Board's acceptance of this agreement, as indicated by the Board President's signature on the attached Order.

13. I am aware of, understand, and have been advised by my counsel of the effect of this Voluntary Surrender.

14. I have read this Voluntary Surrender and I fully understand and acknowledge its facts and terms.

15. I am aware that I have certain constitutional rights, including:

a. I have the right to hire an attorney to represent me in this proceeding;

b. I have the right to demand a hearing on the charges against me, and I can require the Board Staff to prove the allegations;

c. I have the right to cross-examine the witnesses against me;

d. I have the right to call witnesses to provide evidence in my own behalf; and

e. I have other rights accorded to me under Nevada Revised Statutes Chapters 233B, and 6329. Also, I have rights accorded to me under Nevada Administrative Code Chapter 639.

16. I am aware of the foregoing rights, and I voluntarily, knowingly, and intelligently waive these rights in return for the Board accepting my voluntary surrender of my Nevada Pharmacist License in lieu of other disciplinary action.

17. I understand this Voluntary Surrender is considered a disciplinary action and as such will become part of my permanent record.

18. I understand this Voluntary Surrender is considered public information.

19. I understand this Voluntary Surrender is considered a disciplinary action and will be reported to any national repository, which records disciplinary action taken against licensees or certificate holders, or any agency or another state, which regulates the practice of pharmacy.

20. I understand this Voluntary Surrender may be used in any subsequent hearings by the Board as evidence against me to establish a pattern of behavior and for the purpose of proving additional acts of misconduct.

21. This Voluntary Surrender shall not be construed as excluding or reducing any criminal or civil penalties or sanction or other remedies that may be applicable under federal, state or local laws.

22. I understand that this surrender is effective the day it is accepted by the Nevada State Board of Pharmacy, however, I agree to immediately cease and desist from practicing pharmacy, and I will immediately return my certificate/registration with this signed Voluntary Surrender of License In Lieu of Other Disciplinary Action, to the extent I have that certificate/registration in my possession.

23. I understand that as an unregistered pharmacist, I may not access or be present in the drug storage area or personal information storage area of any pharmacy at any time without a Nevada licensed pharmacist present. Upon the Board's acceptance of this agreement, I will turn over all keys and other means of access to the drug storage areas and personal information storage areas of both Meadow Valley Pharmacy and Pahranagat Valley Pharmacy, which I currently own, to the managing pharmacist of those pharmacies.

24. If I, at any time, seek to obtain a new license or registration with the Board, I may be required to appear before the Board, which may ask me questions regarding my application, the allegations in this action, and/or any other circumstances surrounding the surrender of my registration.

I, ADAM P. KATSCHKE R.Ph., Certificate of Registration No. 15601, by affixing my signature below, agree with the foregoing facts and representations, and hereby elect to voluntarily surrender my Nevada pharmacist license.

AGREED:

SIGNED this 6 day of October, 2016

ADAM P. KATSCHKE, R.Ph.
Certificate of Registration No. 15601

State of Nevada
County of CLARK

This instrument was acknowledged before me on October 6th, 2016, by ADAM P. KATSCHKE.

NOTARY PUBLIC
KIMBERLY J. LaPOINTE
STATE OF NEVADA - COUNTY OF CLARK
MY APPOINTMENT EXP. FEB 9, 2020
No: 00-67877-1

Notary Public

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby accepts the voluntary surrender of ADAM P. KATSCHKE's Nevada Pharmacist License, Certificate of Registration No. 15601, in Case No. 15-017-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

10/12/16
Dated

Leo Basch, President
Nevada State Board of Pharmacy

FILED
2847
SEP - 9 2016
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	**CASE NO. 15-017-RPH-S**
	CASE NO. 15-017-PT-S
Petitioner,	**CASE NO. 15-017-PH-S**
v.	
ADAM KATSCHKE, RPH	**NOTICE OF INTENDED ACTION**
Certificate of Registration No. 15601,	**AND ACCUSATION**
ANGELA WALKER, PT	
Certificate of Registration No. PT06113, and	
MEADOW VALLEY PHARMACY	
Certificate of Registration No. PHN01728,	
Respondents.	

Larry L. Pinson, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes (NRS) 233B.127(3), and as an accusation under NRS 639.241.

I.

The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at all times relevant to the allegations and events alleged herein, Respondent ADAM PAUL KATSCHKE, R.Ph. (Mr. Katschke), Certificate of Registration No. 15601, was a pharmacist registered with the Board; Respondent ANGELA WALKER, PT (Ms. Walker), Certificate of Registration No. PT06113, was a registered pharmaceutical technician with the Board; and Respondent MEADOW VALLEY PHARMACY (Meadow Valley Pharmacy), Certificate of Registration No. PHN01728, held a pharmacy license issued by the Board.

II.

In March 2015, Board Staff received a complaint that Mr. Katschke, Angela Walker and Meadow Valley Pharmacy (collectively referred to herein as the "Pharmacy") were unlawfully

dispensing cream based pain medications to patients in Caliente, Nevada, and the surrounding areas, and fraudulently billing those patients' insurers.

III.

The products at issue here are compounded creams containing *Ketamine*, a Schedule III controlled substance used at times to treat pain, and/or *Ketoprofen*, a nonsteroidal anti-inflammatory dangerous drug. The products are referred to collectively herein as "Pain Cream".

IV.

During the course of a joint investigation involving investigators from the Board and from the Nevada State Board of Medical Examiners (BME), Angela Walker admitted verbally and in writing to various activities that violate Nevada statutes and/or regulations.

V.

Ms. Walker is a pharmaceutical technician. She is not a licensed pharmacist, although she has claimed to be the pharmacy manager.

VI.

Ms. Walker marketed Pain Cream to residents of Caliente, Nevada, and the surrounding areas, by offering those patients samples of the Pain Cream and soliciting orders for tubes of the medication.

VII.

When a patient showed interest in obtaining additional Pain Cream, Ms. Walker's practice was to represent to them that their insurance would pay for the medication and that the Pharmacy would waive the patient's co-pay.

VIII.

Ms. Walker would then contact, or claim to contact, one of four prescribers—Dr. Katschke (Mr. Katschke's brother), Dr. Luedeman, Dr. Rogers or Mr. Anderson, PA—to request approval to process a "prescription" and provide the patient with additional Pain Cream.

IX.

It eventually became the Pharmacy's practice to attribute prescriptions for Pain Cream to one of those four prescribers without the prescriber's knowledge or consent, thereby falsely representing that a prescriber had issued a valid prescription.

X.

The Pharmacy used those prescriber's DEA numbers without their knowledge or consent.

XI.

The Pharmacy initially used Ketamine powder to compound the Pain Cream. Once a provider(s) ceased to pay for Ketamine powder, the Pharmacy switched to billing the insurance companies for Ketamine *tablets*, but continued to compound using the *powder*.

XII.

The *tablet* form of Ketamine is more expensive, and thus merits a higher reimbursement, than Ketamine *powder*.

XIII.

According to Ms. Walker, most patients liked and wanted the Pain Cream until they saw the amount the Pharmacy billed their insurers for the compounded medication.

XIV.

Many times the Pharmacy billed multiple patients' insurers for Pain Cream, but did not make or dispense Pain Cream to the patients.

XV.

The Pharmacy often billed patients' insurers for the Pain Cream without the patients' knowledge.

XVI.

At times, the Pharmacy billed insurers for Pain Cream prescriptions for each member of entire families, including children, and including Ms. Walker's family, for Pain Cream without the patients' knowledge, without a prescription and at times without dispensing any medication.

XVII.

Most of the employees for the Pharmacy allowed the Pharmacy to bill their insurance carriers for Pain Cream that the Pharmacy did not dispense.

XVIII.

The Pharmacy's practice was to refill patients' Pain Cream "prescriptions" until the patient asked the Pharmacy to stop.

XIX.

Per Ms. Walker's verbal and written statements, Mr. Katschke knew and consented to the Pharmacy's activities. He knew that the Pharmacy billed insurers for products the Pharmacy never compounded or dispensed.

XX.

According to Ms. Walker, the Pharmacy paid her commissions of approximately $100,000 in 2014, resulting from her Pain Cream sales.

XXI.

Ms. Walker maintains that the Pharmacy did not compensate any of the above named prescribers for the prescriptions the Pharmacy attributed to them.

XXII.

During the Board and the BME's joint investigation, Ms. Katschke corroborated many of Ms. Walker's statements and likewise admitted to activities that violate Nevada statutes and/or regulations.

XXIII.

Mr. Katschke is a licensed pharmacist, the sole owner of the Pharmacy and the pharmacy manager of Meadow Valley Pharmacy.

XXIV.

After obtaining training from Professional Compounding Centers of America (PCCA) in non-sterile compounding, Mr. Katschke, through the Pharmacy, began marketing Pain Cream to patients by contacting them, providing a "sample" and offering to obtain a prescription for more Pain Cream.

XXV.

Mr. Katschke knew that the Pharmacy was attributing prescriptions for Pain Cream to Dr. Katschke, Dr. Luedeman, Dr. Rogers and/or Mr. Anderson without their knowledge.

XXVI.

Mr. Katschke maintains that the prescribers were not aware of the prescriptions the Pharmacy processed using their names and DEA numbers.

XXVII.

The Pharmacy often did not verify that a doctor/patient relationship existed between the patient and the prescriber to whom the Pharmacy attributed many Pain Cream prescriptions.

XXVIII.

Mr. Katschke was aware that the Pharmacy was billing many prescriptions for Pain Cream without valid prescriptions.

XXIX.

Mr. Katschke was aware that the Pharmacy was not compounding many of the Pain Cream prescriptions that it billed to insurers.

XXX.

Mr. Katschke knew that the Pharmacy was billing insurers for products that the Pharmacy did not dispense.

XXXI.

The Pharmacy paid Ms. Walker a commission of three percent (3%) of the money paid by insurers for the compounded Medication.

XXXII.

Mr. Katschke stated that in 2014, the Pharmacy paid Ms. Walker a salary of approximately sixty thousand dollars ($60,000), resulting in payments to her in excess of two hundred thousand dollars ($200,000) in combined salary and commissions.

XXXIII.

Each prescriber, through his counsel, provided statements affirming that the majority of the Pain Cream prescriptions the Pharmacy filled using their names and DEA numbers were not authorized by the prescriber and fraudulent.

XXXIV.

In July 2016, Nevada Attorney General Adam Laxalt charged Mr. Katschke with one count of *Insurance Fraud in violation of NRS 686A.2815(2)*, and one count of *Submitting False Claim: Medicaid Fraud, in violation of NRS 422.540(1) and 422.540(2)(a)*. In August 2016, Mr. Katschke signed a *Memorandum of Plea Negotiations* (Memorandum) pleading guilty to those criminal charges.

XXXV.

FIRST CAUSE OF ACTION
(All Respondents – Felony: Dangerous Drugs)

"A person who knowingly . . . [f]ills a prescription which is not genuine . . . is guilty of a category E felony . . . ." *See* NRS 454.311. Similarly, it is a category D felony in Nevada for a person to "furnish[*sic*] any dangerous drug [to another person] . . . unless the dangerous drug was obtained originally by a legal prescription." NRS 454.221(1). If a person is guilty of a felony relating to a license or registration he or she holds pursuant to NRS Chapter 639, or other crime involving moral turpitude, dishonesty or corruption, that is grounds on which the Board may revoke or suspend any license or registration it issued. *See* NRS 639.210(7). By admitting to dispensing Pain Cream containing Ketoprofen, a dangerous drug, without the knowledge or consent of either the indicated prescriber or the indicated patient, and thus without a prescription,

Respondents Mr. Katschke, Ms. Walker and Meadow Valley Pharmacy, and each of them, is guilty of violating NRS 454.311 and NRS 454.221(1). Those violations are grounds for discipline, including suspension or revocation, of each Respondent's license or registration. (*See* NRS 639.210(7) and NRS 639.255.

XXXVI.

SECOND CAUSE OF ACTION

(All Respondents – Felony: Controlled Substances)

"It is unlawful for a person knowingly or intentionally to . . . . [u]se in the course of the manufacture or distribution of a controlled substance a registration number which is . . . issued to another person." NRS 453.331(1)(b). It is also "unlawful for a person to knowingly or intentionally . . . [s]ign the name of . . . another person on any prescription for a controlled substance or falsely make, alter, forge, utter, publish or pass, as genuine, any prescription for a controlled substance." NRS 453.331(1)(f).

"A person who violates [NRS 453.331] is guilty of a category C felony . . . ." NRS 453.331(2). If a person is guilty of a felony relating to a license or registration he or she holds pursuant to NRS Chapter 639, or other crime involving moral turpitude, dishonesty or corruption. that is grounds on which the Board may revoke or suspend any license or registration it issued. *See* NRS 639.210(7).

By admitting to dispensing medicated Pain Cream containing Ketamine, a Schedule III controlled substance, using the names and DEA numbers of the prescribers identified above, without the knowledge, consent or a genuine prescription from the prescriber. Respondents Mr. Katschke, Ms. Walker and Meadow Valley Pharmacy, and each of them, is guilty of violating NRS 453.331(1)(b) and (f). Per NRS 453.331(2), those violations constitute a category C felony, and are grounds for discipline against each respondent's license or registration pursuant to NRS 639.210(7) and or NRS 639.255.

XXXVII.

THIRD CAUSE OF ACTION
(All Respondents – Felony: Controlled Substances)

> The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter . . . if the holder . . . :
>
> 1. Is not of good moral character;
>
> . . . .
>
> 4. Is guilty of unprofessional conduct or conduct contrary to the public interest;
>
> . . . .
>
> 12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit;

NRS 639.210. Black's Law Dictionary defines the phrase "good moral character", in part, as:

> [a] pattern of behavior that is consistent with the community's current ethical standards and that shows an absence of deceit or morally reprehensible conduct .... A pattern of behavior conforming to a profession's ethical standards and showing an absence of moral turpitude. Good moral character is usu[ally] a requirement of persons applying to practice a profession such as law or medicine.

BLACK'S LAW DICTIONARY 714 (8th ed. 2000). Unprofessional conduct includes:

> Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles (NAC 639.945(g)), and "[p]erforming or in any way being a party to any fraudulent or deceitful practice or transaction" (NAC 639.945(h)).

By admitting to dispensing medicated Pain Cream containing a dangerous drug and/or a controlled substance, namely Ketamine and/or Ketoprofen, without a prescription, and fraudulently billing insurers for those "prescriptions" without actually dispensing any product to the patient named on the "prescription" and bill, Mr. Katschke, Ms. Walker and Meadow Valley Pharmacy, and each of them, have demonstrated grounds pursuant to NRS 639.210(1), (4) and (12) to discipline, including revoking or suspending, their respective licenses or registrations.

XXXVIII.

FOURTH CAUSE OF ACTION

(Adam Katschke – Felony: Insurance Fraud and Medicaid Fraud)

If a person is convicted of a felony relating to a license he holds pursuant to NRS Chapter 639, or other crime involving moral turpitude, dishonesty or corruption, that conviction is grounds on which the Board may revoke or suspend any license or registration it issued. *See* NRS 639.210(7). By pleading guilty to Insurance Fraud, a category D felony in violation of NRS 686A.2815, and to Submitting False Claims: Medicaid Fraud, a category D felony in violation of NRS 422.540, Respondent Adam Katschke has been convicted of a felony relating to his pharmacist license, as well as crimes involving moral turpitude, dishonesty and corruption. *See* NRS 639.006. Mr. Katschke's convictions are therefore grounds for discipline against his pharmacist license pursuant to NRS 639.210 and/or NRS 639.255, up to, and including, suspension or revocation.

XXXIX.

FIFTH CAUSE OF ACTION

(Adam Katschke – False Claims: NRS 639.2815)

> A pharmacist or practitioner who knowingly submits to the State or any of its political subdivisions or any agent thereof, a charge or claim for drugs or medical supplies furnished to or for a person receiving medical care under any program of public assistance, which is false or which is in excess of any amount established by law or regulations adopted by the Department of Health and

> Human Services or by the governing body of any political subdivision, as the price or fee for the furnishing of those drugs or medical supplies, is guilty of a category D felony . . . .

NRS 639.2815.

Respondent Mr. Katschke pleaded guilty to Submitting False Claims: Medicaid Fraud, a category D felony in violation of NRS 422.540, in the Criminal Action. (Case No. CR071016.) In doing so, Mr. Katschke admitted to knowingly submitting charges and claims that are false to the State and its political subdivisions, namely Medicaid, which actions violate NRS 639.2815. Those actions are grounds for discipline against Mr. Katschke's pharmacist license, up to, and including, suspension or revocation, pursuant to NRS 639.210(7) and/or NRS 255.

XL.

SIXTH CAUSE OF ACTION

(Adam Katschke – Managing Pharmacist Responsibilities)

"The Board may suspend or revoke any . . . license. . . issued pursuant to this chapter . . . if the holder . . . [h]as, as a managing pharmacist . . . has knowingly allowed a violation of any provision of this chapter or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision." NRS 639.210(15). Mr. Katschke, as the owner and managing pharmacist of the Pharmacy, knowingly allowed the violations of Nevada State Law as alleged in the foregoing paragraphs. Mr. Katschke's pharmacist license is therefore subject to discipline, including suspension or revocation, pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 9th day of September, 2016.

J. David Wuest, Deputy Executive Secretary
Nevada State Board of Pharmacy on behalf of
Larry L. Pinson, Executive Secretary

GG. City Pharmacy – Las Vegas
HH. Sav-on Pharmacy #2804 – Las Vegas

After discussion the Board instructed Board Staff to have Paragon Healthcare Specialty (Item G) appear for next Board meeting to clarify their services provided and discuss information presented on the company website.

Board Action:

Motion: Cheryl Blomstrom moved to approve the Consent Agenda with the exception of Item G.

Second: Jason Penrod

Action: Passed unanimously

4. Discipline

A.	Adam Katschke, R.Ph	(15-017-RPH-S)
B.	Angela Walker, PT	(15-017-PT-S)
C.	Meadow Valley Pharmacy	(15-017-PH-S

Dan Albregts was present as counsel representing Adam Katschke and Meadow Valley Pharmacy.

Mr. Edwards stated that Angela Walker was not present. He explained that the set of facts is common for all three cases.

Mr. Edwards explained that Board Staff received a complaint in March 2015, that Mr. Katschke, Ms. Walker and Meadow Valley Pharmacy were illegally dispensing ketamine and ketoprofen cream to patients in Caliente, NV. Mr. Edwards stated that Ms. Walker, pharmacy technician, claimed to be the pharmacy manager and marketed the pain cream to patients by offering samples and soliciting prescriptions for tubes of medication. If a patient showed interest in buying more pain cream Ms. Walker would tell them that their insurance would cover the medication and the pharmacy would waive any copays. Initially Ms. Walker would contact physicians to solicit prescriptions on behalf of the patients, but eventually the pharmacy began to falsify prescriptions and attribute the fake prescriptions to prescribers without the prescriber's knowledge. The pharmacy initially used ketamine powder to compound the pain cream. Once the insurance companies started to reject payments for the ketamine powder the pharmacy billed insurance for ketamine tablets, but continued to use ketamine powder for compounding.

Mr. Edwards explained that during this time, Mr. Katschke was the sole owner of Meadow Valley Pharmacy and a registered pharmacist. He is also the owner of Pahranagat Pharmacy. Mr. Katschke was aware of the actions Ms. Walker was doing, and Meadow Valley Pharmacy paid Ms. Walker a commission of 3% of the money paid by insurance. Ms. Walker made somewhere between $100,000 and $200,000 during 2015. In July 2016, the Nevada Attorney General's Office charged Mr. Katschke with one count of insurance fraud,

submitting false claims and Medicaid fraud. Mr. Katschke pleaded guilty to those criminal charges.

Mr. Edwards stated that Causes of Action 1 through 3 applied to all Respondents, and the Causes of Action 4 through 6 apply to Mr. Katschke.

Mr. Albregts agreed with Mr. Edwards description of the case.

Mr. Edwards presented a Stipulation and Order regarding the Mr. Katschke and Meadow Valley Pharmacy. Those Respondents admit that evidence exists to establish a basis for the violations alleged in the Accusation.

Mr. Katschke shall surrender his Nevada Pharmacist License, pay an administrative fee of $10,000 and sell both Meadow Valley Pharmacy and Pahranagat pharmacy.

Meadow Valley Pharmacy shall surrender its Nevada Pharmacy License, Trent Decker shall be the new managing pharmacist, and Pahranagat Pharmacy will surrender its Pharmacy License within 90 days or at point-of-sale. Adam Katschke is not allowed access to the pharmacy and any proposed new owners will appear at the December or January Board meeting.

Mr. Albregts added that additional fees and restitutions are being paid to the Nevada Attorney General's Office to cover their investigation costs. He anticipated the pharmacy sale to be complete prior to January.

Mr. Edwards stated that there are restrictions on the pharmacy sale and explained that the pharmacy could not be owned by Mr. Katschke's immediate family.

Mr. Albregts urged the Board to accept the Stipulation and Order.

Board Action:

Motion: Jason Penrod moved to accept the Stipulation and Order regarding Adam Katschke as presented.

Second: Cheryl Blomstrom

Action: Passed unanimously

Board Action:

Motion: Jason Penrod moved to accept the Stipulation and Order regarding Meadow Valley Pharmacy as presented.

Second: Cheryl Blomstrom

Action: Passed unanimously

President Basch called for Angela Walker. Ms. Walker was not present.

Mr. Edwards moved to have Exhibits 1 & 2 entered into the record.

President Basch accepted the Exhibits into the record.

Mr. Edwards stated that Exhibits 1 & 2 are Ms. Walker's Notice of Intended Action and Accusation and a follow up letter informing her of the date and time of her hearing. Both documents were sent by Certified Mail.

Board Action:

Motion: Jason Penrod moved to find that based on the evidence presented, Board Staff properly attempted service to Ms. Walker.

Second: Darla Zarley

Action: Passed Unanimously

Mr. Edwards explained that Ms. Walker has not contacted Board Staff, nor has counsel contacted Board Staff on her behalf.

Mr. Edwards requested permission to move forward with the default proceedings.

President Basch approved.

Board Action:

Motion: Jason Penrod moved to find Angela Walker guilty by default

Second: Darla Zarley

Action: Passed unanimously

Mr. Edwards stated that Board Staff recommends revocation of Ms. Walker's pharmaceutical technician registration.

Board Action:

Motion: Jason Penrod moved to revoke Angela Walker's Pharmaceutical Technician License. Board Staff is directed to refer this case to law enforcement.

Second: Darla Zarley

Board Staff offered a recommendation that Ms. Walker pay an administrative fee of $1,000.00.

Mr. Penrod and Ms. Zarley accepted the recommendation.

Action: Passed unanimously

D.	Michael Lesser, R.Ph	(16-024-RPH-A-S)
E.	Stephan Cho, R.Ph	(16-025-RPH-B-S)
F.	Walgreens #07164	(16-024-PH-S)

Tallie Pederson recused due to her employment with Walgreens.

Darla Zarley disclosed that Stephan Cho was a former student, but stated that she would be able to participate in this matter fairly and without bias.

Michael Lesser, Stephan Cho and Jaclyn Latteri, Walgreens District Manager, appeared and were sworn by President Basch prior to answering questions or offering testimony.

Bill Stilling was present as counsel representing the Respondents.

Mr. Stilling stated that Nicole Cramer, pharmaceutical technician, was present in the audience. Ms. Cramer was subpoenaed for her involvement in this case.

Mr. Edwards explained this case involves two errors on the same patient with the same medication. He stated that in July 2015, the patient's pediatrician prescribed a quantity of thirty (30) montelukast 4 mg. chewable tablets with 6 refills. In February 2016, Walgreens processed an automatic refill for this prescription. The patient's mother picked up the prescription. Upon opening the bottle, she realized the tablets were square rather than the rectangular tablets she was accustomed to for her son's montelukast 4 mg. chewable tablets. She discovered that the prescription was filled for montelukast 5 mg. chewable tablets instead of montelukast 4 mg. tablets a prescribed. Her son and his twin brother each ingested two tablets of the erred medication with no reported adverse effects. Mr. Lesser filled the prescription and performed final product verification of the product. He failed to detect that the bottle contained the incorrect medication.

Mr. Edwards stated that on March 15, 2016, the pediatrician wrote a new prescription for the same patient for 30 montelukast 4 mg. chewable tablets with 6 refills. The patient's mother picked up the medication and again discovered that the tablets were square rather than rectangular. Walgreens again dispensed montelukast 5 mg. chewable tablets rather than the montelukast 4 mg. chewable tablets as prescribed. Pharmacy records show Ms. Cramer correctly performed data entry which was verified remotely at a Walgreens' Central Facility in Florida, but pharmacy security video shows Ms. Cramer filled the prescription with the incorrect 5 mg. dosage and manually entering in the NDC when the stock bottle failed to scan. Mr. Cho performed final product verification and counseling. Mr. Cho did not detect the error.

Mr. Edwards presented a Stipulation and Order regarding the Respondents. The Respondents admit that evidence exists to establish a basis for the violations alleged in the Accusation.

Details for Adam Paul Katschke

License Information

Name:	Adam Paul Katschke
City, State, Zip, Country:	Caliente NV 89008 United States
Profession:	Pharmacy
License Type:	Pharmacist
License Number:	4762546-1701
Obtained By:	Application
License Status:	Surrendered
Original Issue Date:	06/26/2000
Expiration Date:	02/16/2017
Agency and Disciplinary Action*:	YES View Actions
Docket Number:	2017-109

Controlled Substance License	Yes View Controlled Substance License

Education:

School Name	Major	Graduation Date	Degree
Creighton University	PhD of Pharmacy	2000-05-13	

This information is accurate as far as is contained in the Division's official records. It does not reflect whether an entity required to maintain a current registration with the Division of Corporations is current in that registration. You can verify such status at https://secure.utah.gov/bes/bes. Additionally, this verification does not show a complete license history or interruptions of licensure. Original issue dates listed as 01/01/1910 and 01/01/1911 were unknown at the time the Division implemented its first electronic licensing database.

*NOTE: The disciplinary documents linked to this website include final orders issued by DOPL, with the exception of citations. Click here for citations.

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
SEAN D. REYES (U.S.B. 7969)
Utah Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 140872
Salt Lake City, UT 84114-6741
Telephone: (801) 366-0310

BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF **ADAM PAUL KATSCHKE** UTAH LICENSE #4762546-1701 and 8911 TO PRACTICE AS A PHARMACIST AND TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH	))))))	**SURRENDER** **STIPULATION AND ORDER** CASE NO. DOPL 2017-109

ADAM PAUL KATSCHKE ("Respondent") and the Division of Occupational and Professional Licensing of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby knowingly and intelligently waives the right to all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R156-4-901 through R156-4-907. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent acknowledges that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's licenses, to other persons and entities.

7. Respondent admits the following facts are true:

a. On or about June 26, 2000, Respondent was first licensed to practice as a pharmacist and to dispense controlled substances in the State of Utah.

b. On or about October 6, 2016, Respondent entered into a "Voluntary Surrender of Registration/Certificate in Lieu of Other Disciplinary Action," along with the associated Notice of Intended Action and Accusation, with the Nevada State Board of Pharmacy, a copy of which is incorporated by reference into this Stipulation and Order, and attached as Exhibit A.

c. The misconduct described in Exhibit A would also constitute misconduct in the State of Utah.

d. In 2016 Respondent pleaded guilty to one count of insurance fraud, a Category D felony, and one count of submitting a false Medicaid claim, a Category D felony, in the Seventh Judicial District Court, Lincoln County, Nevada.

e. Respondent desires to surrender Respondent's licenses to practice as a pharmacist and to dispense controlled substances in the State of Utah along with all residual rights pertaining to said licenses.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a), (c), and (d); and that said conduct justifies disciplinary action against Respondent's license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent hereby surrenders Respondent's licenses to practice as a pharmacy and to dispense controlled substances in the State of Utah along with all residual rights pertaining to said licenses. Respondent agrees that the issuance of the Order in this matter constitutes disciplinary action by the Division pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. § 58-1-401(2)(a). Respondent agrees not to reapply for licensure to practice pharmacy or to dispense controlled substances in the State of Utah for five years from the effective date of this Stipulation and Order. The Division does not guarantee than any future

application by Respondent for licensure will be granted. If the Division Director accepts the terms of this Stipulation and Order, Respondent forfeits all rights to practice as a pharmacist and to dispense controlled substances in the State of Utah. Respondent understands that Respondent will not receive any refund of license or renewal fees previously paid to the Division.

9. This Stipulation and Order, upon approval by the Director of the Division, shall be the final compromise and settlement of this non-criminal administrative matter. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of the Director having reviewed this Stipulation, and this waiver shall survive such nullification.

10. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation.

11. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law.

12. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

13. Respondent understands and agrees that if Respondent has been issued an Order by the Division to pay an administrative penalty or a fine, and Respondent has not paid the administrative penalty or fine in full at the time this Stipulation and Order becomes effective, then Respondent may not reapply for licensure in the State of Utah, in any profession or occupation, until Respondent has paid the administrative penalty or fine in full. Respondent understands and agrees that any application for licensure submitted by Respondent shall be denied for the reason of failure to pay an administrative penalty or fine by the Division until Respondent has paid the administrative penalty or fine in full. The Division may also deny the license for any other lawful reason. Respondent understands and agrees that this surrender of Respondent's license(s) does not extinguish any obligation Respondent has to pay any administrative penalty or fine previously ordered by the Division.

14. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

BY: _____
DANE ISHIHARA
Bureau Manager

DATE: 2-15-2017

RESPONDENT

BY: _____
ADAM PAUL KATSCHKE

DATE: 2/8/17

SEAN D. REYES
UTAH ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 15 Feb 17

ORDER

The Stipulation above, in the matter of ADAM PAUL KATSCHKE, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(7) and Utah Code Ann. §58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

Dated this 16 day of February, 2017

Mark B. Steinagel
Director
Division of Occupational
and Professional
Licensing

Mark I. Sedar

From: adam katschke <[redacted]
Sent: Thursday, April 29, 2021 9:31 AM
To: Mark I. Sedar
Subject: License application
Attachments: NDOCAdam.pdf

Hello Mark,
Thank you for the phone call the other day and for the Board's attention to my matter. I have attached several documents for the review of the Board in my case. The first form is a copy of my original sentence; pages 2-4 are what I received from the parole board while incarcerated; and the last page is what I received from Parole and Probation when my sentence had expired. Pages 2-4 are dark because they were given to me on yellow carbon copy paper.

If I may, I would like to give a brief synopsis of the documents. I entered into a plea deal and was sentenced in January of 2017. The first page shows what my crimes were and what sentence was expected. I plead to one count of insurance fraud and one count of Medicaid fraud. The judge sentenced me to two counts of 12-48 months to be served concurrently. My earliest parole date was June of 2017. The next three pages show the decision of the parole board - I was to receive parole but not until January of 2018. The final page shows the end of my parole in November 2018.

I spent approximately one year in custody of NDOC and ten months on parole. The first two months of my sentence were spent in High Desert State Prison in Indian Springs, NV, and the rest of my sentence was spent in Ely Conservation Camp. In Ely, it is a work camp and there is a full-time teacher. I was eventually assigned to be his Education Clerk, where I was able to assist inmates in working towards their GED and High School Diploma. There were many who were able to receive those certificates while I was there. I do not want to talk a lot about my time in prison but am willing to answer any questions that the board may have.

I did take a plea for my case. I would like to clarify some of the situations in regards to my plea. At the time of the fraud occurring in Meadow Valley Pharmacy, I had hired a pharmacy manager and two full-time pharmacists to run the business. I was a county commissioner and had several other small businesses that my wife and I ran. Of the two pharmacists, I should have chosen one to be the Managing Pharmacist. Unfortunately, with their bickering and hurt feelings over who should be in that position, I left myself as the managing pharmacist. I also had several family members in leadership positions in our community. As I still claim that I did not participate in fraudulent activities or ask that anyone else commit fraud, I felt responsible as the owner of the pharmacy. I hired legal counsel with the idea of making things right. As the judge and AG's office saw it, I was the "mastermind". I was way too busy in my life and was extremely neglectful of my duties and obligations in the pharmacy. I rarely came to work due to my schedule. Although I felt that I was wrongfully sentenced and convicted, I served the time and took my lumps. I have learned a lot about trust and responsibility as a result of my time away from pharmacy.
I am respectfully requesting to be allowed to obtain my license once again, but the Board should know that even if I receive my Pharmacy License, it will be an uphill battle for me. As I accepted a Medicaid Fraud Plea (although total Medicaid sales were only $30,000 over 3 years), I have now added myself to the OIG watchlist. This means that nobody can hire me if they process Medicare or Medicaid prescriptions. It will be nearly impossible to gain employment. I also have an Insurance Fraud conviction, which means that until the year 2023, any employer would have to acknowledge that fact and would not receive certain insurance contracts because of me. I am primarily applying for licensure to be able to stay prepared for the future, if an when these items go away. I would like to be able to do CE and keep more up-to-date with clinical and pharmacy issues. Eventually, I would like to work again in my area of expertise and education.
Thank you for the opportunity to come before the Board. Please direct any questions to me that you would like answered. There is obviously a lot of details and other items left out in order to keep this as brief as possible. Thank you. ADAM

--
Adam P Katschke, PharmD
[redacted]Haystack Lane [redacted]
Caliente, NV 89008
Cell# [redacted]

DIVISION OF PAROLE AND PROBATION

HEADQUARTERS
1445 Old Hot Springs Road, Suite 104
Carson City, NV 89706

November 04, 2018

Adam Katschke
[redacted]HAYSTACK LANE/[redacted]
CALIENTE, NV 89008

Case Number: CR-0717016
Re: Outstanding Financial Obligations
BIN Number: 1004276002

Mr. or Mrs. KATSCHKE:

You discharged/expired your term on November 04, 2018. Your remaining unpaid balance due and payable within 30 days from the date of this letter is listed below:

Supervision Fees:	$0.00
House Arrest:	$0.00
Drug Test:	$0.00
Psych Test:	$0.00
Extradition:	$0.00
DNA fee:	$0.00
Total Amount Due:	**$0.00**

Please remit payment in the form of a Money Order, Cashier's Check, or personal check made payable to: Division of Parole and Probation. Do not leave the payee line or the "Pay to the Order of" line blank. Alternatively, you may pay by e-check by calling (775) 684-2614 during the hours of 8:00 a.m. to 4:30 p.m., Monday through Friday (closed on all public holidays). Please have your bank account and routing number available. Do not make payments with cash. Keep a copy of your payment for your records. Print your name and BIN number under your signature for proper identification.

Mail your payment to:
Division of Parole and Probation
1445 Old Hot Springs Rd., # 104
Carson City, NV 89706

If the above total amount is not received by the Division of Parole and Probation within 30 days from the date of this letter, your account will be turned over to the State Controller and/or an independent collection agency as allowed by Nevada Revised Statutes (NRS) Chapter 353C. In addition, pursuant to NRS 353C.135, a collection agency may charge collection costs and fees up to 35% of the debt owed or $50,000.00, which ever is less.

This is your final notice from the Division of Parole and Probation.

Respectfully,

Nevada Division of Parole & Probation
Fiscal Services

Ely Conservation Camp
HC 10 Box 10813
Ely, NV 89301

To:

From: Katschke, Adam NDOC #: 1173026

DOB: [redacted] SS# [redacted]

Re: Case No. (s):

CR071016 1 Ins fraud	06/23/2017 10/10/2018 LIN A 0	MAX:	(0yr 48mo 0dy)
		MIN:	(0yr 12mo 0dy)
CR071016 2 Swindle credit by false rep, $650+Swindle credit by false representation, value $650 or greater	06/23/2017 10/10/2018 LIN A 0	MAX:	(0yr 48mo 0dy)
		MIN:	(0yr 12mo 0dy)

Charge(s): 12-48 Months NDOC

In reference to the above case(s), the undersigned states that I have been incarcerated since 10/01/2016.

The following information is supplied by the Nevada Department of Corrections and verified by the Caseworker.

1. Date of Incarceration: 01/13/2017
2. Term of Incarceration: 12-48 Months
3. Expiration of Sentence: 10/10/2018
4. Parole Eligibility Date 06/23/2017

Russell Lyons CCWS
Signature of Caseworker

I, the undersigned, state that I am hereby willing to accept the decision of this Board, and have acknowledged that the above information is correct. I sign under Penalty of Perjury.

Signature of Inmate.

STATE OF NEVADA
CERTIFICATION OF
BOARD OF PAROLE COMMISSIONERS ACTION

ORDER GRANTING PAROLE

KATSCHKE, ADAM PAUL	1173026	2017-085408	ECC-U1-A-4-I	06/05/2017
Inmate Name	*NDOC Number*	*Booking #*	*Location*	*Date*

It is the Order of the Board that Parole is GRANTED. The effective date of parole is: 01/13/2018

Release to the community or to a consecutive sentence is authorized on the above specified date. If "when eligible" is indicated, release is authorized on or after the date of this hearing upon attaining minimum eligibility, as determined by the Nevada Department of Corrections (NDOC). Release to the community may not occur until approval of release plans in accordance with NRS 213.140.

You are expected to program and/or work constructively regardless of institutional setting, and you are expected to abide by the rules of the NDOC. Failure to work and/or program constructively, or violation of the rules of the NDOC may result in the rescission of this order and denial of parole.

NOTE. A parolee who violates a condition of his or her parole forfeits all or part of the credits for good behavior earned by the parolee after release on parole at the discretion of the Board. A parolee whose parole is revoked for having violated a condition of parole forfeits all credits for good behavior previously earned to reduce his or her sentence pursuant to NRS 209. The Board may restore any forfeited credits at its discretion.

THIS ACTION APPLIES TO THE FOLLOWING SENTENCE(S):
*Controlling sentence denoted by *. Case #: Count: Offense Description*
CR071016;2;FALSE REPRESENTATION TO DEFRAUD
CR071016;1;INSURANCE FRAUD

Reason(s) for action:
Grant Reason. The parole guideline recommends that parole be granted, and there are no serious reasons to deviate from the guideline recommendation.
Grant Reason. There is community and/or family support.
Grant Reason. The inmate has stable release plans.
Grant Reason. The inmate has no prior or minimal criminal conviction history.

Recommendation of the panel who conducted the hearing: Grant Parole
Commissioner Susan Jackson, Grant Parole
Commissioner Tony Corda, Grant Parole

The final action was ratified by the following Members of the Board of Parole Commissioners:
Commissioner Susan Jackson, Grant Parole
Commissioner Tony Corda, Grant Parole
Commissioner Ed Gray, Grant Parole
Commissioner Michael Keeler, Grant Parole

FOR THE NEVADA BOARD OF PAROLE COMMISSIONERS

This document was prepared by JMEADOR *at 6/6/2017 5:01 PM*

Z_ord_gnt rev 12-14-2016

STATE OF NEVADA
BOARD OF PAROLE COMMISSIONERS
CONDITIONS OF PAROLE SUPERVISION

KATSCHKE, ADAM PAUL	1173026	2017-085408	ECC-U1-A-4-T	06/05/2017
Inmate Name	NDOC Number	Booking #	Location	Date

The following conditions apply to all active parole cases supervised in the community, including any previously granted sentences not specified on this Order of which these conditions replace and supersede.

*Directives: You shall follow the rules of the Division of Parole and Probation to include the following.
*A. You shall not change your place of residence without first obtaining permission from the Division of Parole and Probation.
*B. You shall report in person to the Division of Parole and Probation as instructed by the Division or its agent. You shall submit a written report each month on forms supplied by the Division. This report shall be true and correct in all respects.
*C. You shall seek and maintain legal employment, or maintain a program approved by the Division of Parole and Probation and not change such employment or program without first obtaining permission. All terminations of employment or program shall be immediately reported to the Division.
*D. You shall pay any court ordered restitution by making payments until the balance is paid in full. The minimum monthly payment shall be established by dividing the balance owed at the time of release on parole by the number of projected months to be served on parole. If, after dividing the total restitution owed by the number of projected months to be served on parole the monthly payment is equal to an amount less than $50, the monthly payment shall be $50 until the balance is paid in full.
*E. Pay all applicable fines and fees on a schedule determined by the Division of Parole and Probation.
*F. You shall not leave the state without first obtaining written permission from the Division of Parole and Probation.
*G. You shall not associate with convicted felons, persons who are engaged in criminal activity, or other persons with whom your supervising officer instructs you not to associate.
*H. You shall follow all the directives of your assigned Parole Officer.
*Controlled substances: You shall not use, purchase or possess any illegal drugs, or any prescription drugs, unless first prescribed by a licensed medical professional. You shall immediately notify the Division of Parole and Probation of any prescription received. You shall refrain from the use and possession of any synthetic/designer drug or any mind and/or body altering substance. You shall submit to drug testing as required by the Division or its agent.
*Recreational Marijuana: You shall not purchase, consume or have under your control marijuana in any form, except when such use is prescribed for use as a medicine in accordance with the provisions of chapter 453A of NRS.
*Intoxicants: You shall not purchase, consume or have under your control any alcohol beverage, unless specifically permitted by special condition of the Board. Upon the direction of the Division of Parole and Probation or other peace officer, you shall submit to a medically recognized test for blood/breath content.
*Weapons: You shall not possess, have access to, or have under your control, any type of weapon unless the item is used in conjunction with the duties of legitimate employment and has been approved in writing by the Division of Parole and Probation or its agent.
*Laws: You shall comply with all institutional rules, municipal, county, state, and federal laws and ordinances.

This document was prepared by JMEADOR *at 6/6/2017 5:01 PM*

STATE OF NEVADA
CERTIFICATION OF
BOARD OF PAROLE COMMISSIONERS ACTION

PAROLE RISK ASSESSMENT & GUIDELINE

KATSCHKE, ADAM PAUL	1173026	2017-085408	ECC-U1-A-4-I	06/05/2017
INMATE NAME	NDOC Number	BOOKING#	LOCATION	DATE

Parole Risk Assessment:

Questions	Responses / Scores
1. Age at 1st Arrest	19 years or younger (2): 2
2. Prior Revocations	(0)No Parole or Probation Revocations: 0
3. Employment History	(0)Satisfactory full-time employment for 1-2 years: 0
4. Property Conviction	(2)Auto Theft, Burglary, Forgery, Robbery, Property Crime: 2
5. Drug/Alcohol Use/Abuse	(0)None: 0
6. Gender	(1)Male: 1
Static Risk Score	5
7. Current Age	(-1) 41 and above: -1
8. Gang Membership	(0) No or Suspect: 0
9. Programming (current term)	(0) No: 0
10. Disciplinary Conduct	(-1) No disciplinaries: -1
11. Approved Custody Level	(-1) Minimum: -1
Dynamic Risk Score	-3
Total Score (Static+Dynamic)	2

Offense (used to determine crime severity for risk assessment)	Offense Category	Offense Severity
FALSE REPRESENTATION TO DEFRAUD	CAT D	Moderate

Total Risk Score:	Guideline Risk	Guideline Recommendation
2	Low Risk	Parole at Initial Parole Eligibility

The Board determined the following Aggravating Factors are applicable in your case:
Impact on victim(s) and/or community: Substantial financial loss of over $5 million.

The Board determined the following Mitigating Factors are applicable in your case:
No prior/minimal criminal conviction history.
Community and or family support: Claims family support - Wife in Caliente.
Stable release plans. Indicates confirmed employment and residence.

This document was prepared by JMEADOR *at 6/6/2017 5:01 PM*

received
7-13-16

FILED
2016 JUL 13 PM 2:52
LISA C. LLOYD
LINCOLN COUNTY CLERK
DEPUTY

Case No. CR07170116

Dept. No.

IN THE SEVENTH JUDICIAL DISTRICT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF LINCOLN

THE STATE OF NEVADA,

Plaintiff,

vs.

ADAM PAUL KATSCHKE,

Defendant.

CRIMINAL INFORMATION

Office of the Attorney General
5420 Kietzke Lane, Suite 202
Reno, NV 89511

The undersigned, ADAM PAUL LAXALT, Attorney General of the State of Nevada, by and through his Deputies, RONDA CLIFTON and ANDREW SCHULKE, in the name and by the authority of the State of Nevada, informs the above-entitled court that ADAM PAUL KATSCHKE, the defendant above named, has committed the offenses of:

COUNT I

INSURANCE FRAUD

(Category D Felony - NRS 686A.2815(2))

DEFENDANT ADAM PAUL KATSCHKE, on or about November 14, 2013, to on or about April 9, 2015, within the County of Lincoln, State of Nevada, did knowingly, willfully and unlawfully present or cause to be presented statements as part of, or in support of, claims for payment or other benefits under policies of insurance licensed by this state, known by him to conceal or omit facts, or contain false or misleading information concerning any fact material to those claims, to wit: DEFENDANT, a pharmacist, and owner of Meadow Valley Pharmacy, submitted claims or caused claims to be filed with numerous insurance companies of recipients for compound medication. DEFENDANT knowingly, willfully and unlawfully provided false information in support of claims resulting in voluminous amounts of

compounds being billed to insurance companies that were not prescribed by a physician and/or were not requested by the recipients, and in many instances, the compounds were never received by the recipients.

COUNT II

SUBMITTING FALSE CLAIMS: MEDICAID FRAUD

(Category D Felony - NRS 422.540(1) and 422.540(2)(a))

DEFENDANT ADAM PAUL KATSCHKE, through a scheme or continuous course of conduct, intentionally caused claims to be made for payment from Medicaid that DEFENDANT knew were false, to wit:

From on or about April 2013 to April 2015, DEFENDANT, a pharmacist and owner of Meadow Valley Pharmacy, did knowingly maintain fictitious documentation, including prescriptions, for products allegedly provided to Medicaid recipients. The documentation was used to generate false bills/claims submitted for reimbursement from Medicaid. The documentation maintained by DEFENDANT to substantiate the Medicaid claims was false as many of DEFENDANT'S records did not note the actual quantity or products allegedly provided to the Medicaid recipients. Also, the Medicaid recipients denied that they had received the amount of products allegedly provided by DEFENDANT.

All of which was committed in the County of Lincoln, aggregating an amount in excess of $650.00, and constitutes a category D felony in violation of NRS 422.540.

///

///

///

///

///

///

///

///

///

///

///

Office of the Attorney General
5420 Kietzke Lane, Suite 202
Reno, NV 89511

All of which is contrary to the form, force and effect of the statutes in such cases, made and provided, and against the peace and dignity of the State of Nevada. Therefore, the defendant may be dealt with according to law.

AFFIRMATION PURSUANT TO NRS 239B.030

The undersigned does hereby affirm that the preceding document, CRIMINAL INFORMATION, filed in the Seventh Judicial District Court, State of Nevada v. Adam Paul Katschke, does not contain the social security number of any person.

RESPECTFULLY SUBMITTED this 12th day of July, 2016.

ADAM PAUL LAXALT
Attorney General

By: Ronda Clifton

RONDA CLIFTON
Senior Deputy Attorney General
Nevada Bar No. 4733
Criminal Justice Bureau
5420 Kietzke Lane, Suite 202
Reno, Nevada 89511
(775) 687-1208
rclifton@ag.nv.gov

By: Ronda Clifton for

ANDREW SCHULKE
Senior Deputy Attorney General
Nevada Bar No. 10218
Criminal Justice Bureau
555 E. Washington Avenue, Suite 3900
Las Vegas, Nevada 89101
(775) 486-3218
aschulke@ag.nv.gov

The following list contains the names and addresses of all witnesses in the matter specified above; known to the Office of the Attorney General at the time the accompanying criminal information was filed.

1. Investigator Dainelle Harris
   Office of the Attorney General
   100 N. Carson Street
   Carson City, NV 89701

2. Investigator Nevada Rhodes
   Office of the Attorney General
   5420 Kietzke Lane, Suite 202
   Reno, NV 89511

Office of the Attorney General
5420 Kietzke Lane, Suite 202
Reno, NV 89511

3. Investigator Matthew Ross
Office of the Attorney General
555 E. Washington Avenue, Suite 3900
Las Vegas, NV 89101

4. Investigator Maggie Figueroa
Office of the Attorney General
555 E. Washington Avenue, Suite 3900
Las Vegas, NV 89101

5. Detective John Cessford
Nevada Division of Investigation

6. Christopher Brewer
Nevada Division of Investigation

7. Tina Italiano
Medco/Express Scripts
One Express Way
St. Louis, MO 63121

8. Fran Shirek
Anthem Blue Cross Blue Shield
700 Broadway
Denver, CO 80273

9. Tammy Nash
OptumRX
2300 Main Street, Ca134-0507
Irvine, CA 92614

10. Special Agent Maxwell Moloney
Dept. of Defense, Inspector General
One North Central Avenue, Suite 1020
Phoenix, AZ 85004

11. Special Agent Jenny Hahn
Office of the Inspector General, Health and Human Services
Las Vegas Office

Office of the Attorney General
5420 Kietzke Lane, Suite 202
Reno, NV 89511

CERTIFICATE OF SERVICE

I certify that I am an employee of the Office of the Attorney General and that on this 12th day of July, 2016, I served a copy of the foregoing CRIMINAL INFORMATION, by causing said document to be placed in the U.S. Mail, postage pre-paid, addressed to:

Daniel J. Albregts, Esq.
601 S. Tenth Street, Suite 202
Las Vegas, NV 89101

Rhonda Collins
An Employee of the Office
of the Attorney General

Office of the Attorney General
5420 Kietzke Lane, Suite 202
Reno, NV 89511

Case No. CR071016

Dept. No. 2

FILED

2017 FEB -9 PM 1:27

LISA [illegible]
LINCOLN COUNTY CLERK

IN THE SEVENTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF LINCOLN

THE STATE OF NEVADA,

Plaintiff,

vs.

ADAM PAUL KATSCHKE,

Defendant.

AMENDED JUDGMENT AND SENTENCE

On August 26, 2016, the above-named Defendant, ADAM PAUL KATSCHKE, pled Guilty to the crimes described below and as more fully set forth in the criminal information filed herein. Legal counsel present at the arraignment was Daniel Albregts, representing the Defendant, and Ronda Clifton, Senior Deputy Attorney General, representing the State.

DESCRIPTION OF CONVICTION

COUNT I - INSURANCE FRAUD - NRS 686A.2815(2)

On January 13, 2017, the above-named Defendant appeared before this Court for the purpose of sentencing and entry of a final judgment of conviction in this matter. This Court, the State and defense counsel had previously received a Pre-Sentence Report, which had been prepared by the Division of Parole and Probation. The above-named Defendant was personally present at the sentencing. Legal counsels present at the Defendant's sentencing were Daniel Albregts, Esq., representing the Defendant, and Ronda Clifton, Senior Deputy Attorney General, and Andrew Schulke, Senior Deputy Attorney General, representing the State. Also present was Matt Hibbs, representing the Division of Parole and Probation.

///

COUNT II – MEDICAID FRAUD - NRS 422.540(1) and NRS 422.540(2)(a)

On January 13, 2017, the above-named Defendant appeared before this Court for the purpose of sentencing and entry of a final judgment of conviction in this matter. This Court, the State and defense counsel had previously received a Pre-Sentence Report, which had been prepared by the Division of Parole and Probation. The above-named Defendant was personally present at the sentencing. Legal counsels present at the Defendant's sentencing were Daniel Albregts, Esq., representing the Defendant, and Ronda Clifton, Senior Deputy Attorney General, and Andrew Schulke, Senior Deputy Attorney General, representing the State. Also present was Matt Hibbs, representing the Division of Parole and Probation.

After hearing from all parties and allowing the Defendant an opportunity to personally address the Court, this Court finds that the appropriate sentence in this case is and shall be as follows:

SENTENCE TERMS

For the conviction of Count I, the defendant is sentenced to a maximum term of forty-eight (48) months within the Nevada Department of Corrections with minimum parole eligibility after twelve (12) months.

For the conviction of Count II, the defendant is sentenced to a maximum term of forty-eight (48) months within the Nevada Department of Corrections with minimum parole eligibility after twelve (12) months. Said sentence shall run concurrent to all prior terms of incarceration against the defendant.

FINANCIAL AND RESTITUTION REQUIREMENTS

In addition to the Administrative Assessment fee of $25.00 for Count I as required by NRS 176.062, Defendant is ordered to pay the $3.00 GMA fee and $150 DNA fee to the Lincoln County Clerk, Pioche, Nevada.

Defendant shall pay restitution in the amount of $1.5 million dollars and reimburse the Attorney General's Office for investigative costs in the amount of $100,000.

ENTRY OF JUDGMENT

IT IS THEREFORE ADJUDGED that the Defendant is guilty of said offense as charged and convicted, and is sentenced to serve for COUNT I – INSURANCE FRAUD, the Defendant is sentenced to a maximum term of forty-eight (48) months within the Nevada Department of Corrections with minimum parole eligibility after twelve (12) months.

For the Conviction to COUNT II – MEDICAID FRAUD, the Defendant is guilty of said offense as charged and convicted, and is sentenced to serve a maximum term of forty-eight (48) months within the Nevada Department of Corrections with minimum parole eligibility after twelve (12) months. Said sentence shall run concurrent to all prior terms of incarceration against the Defendant.

IT IS HEREBY FURTHER ORDERED that in addition to the Three ($3.00) GMA fee and the $150 DNA fee, the Defendant shall pay a Twenty-Five ($25.00) dollar Administrative Assessment fee to the Lincoln County Clerk, Pioche, Nevada. The Defendant shall pay restitution in the amount of $1.5 million and reimburse the Attorney General's Office for investigative costs in the amount of $100,000.

DATED this 7th day of February, 2017.

DISTRICT COURT JUDGE

Mark I. Sedar

From: adam katschke <[redacted]
Sent: Friday, May 14, 2021 2:19 PM
To: Kristopher Mangosing
Cc: Yenh Long; Mark I. Sedar
Subject: Re: FW: License 15601

Hello, everyone. Kris had asked me to put in writing some of the details of my parole and sentencing.

As you may know, the investigation into the practices at my pharmacy started in March or April of 2015. I was a County Commissioner and also ran several small businesses with my wife. I spent very little time at the pharmacy, except for the bills and bookkeeping. I made the mistake of leaving myself as the managing pharmacist, although I had hired two pharmacists to work at Meadow Valley Pharmacy. As there was a lot of discontent among those two pharmacists as to who should be the managing pharmacist, I decided to keep myself as the PIC.

The fraud that took place was done by my store manager at the time. She was called my co-defendant, but it is not a term that I agree with. The pharmacists that I had in place never talked to me about things that may seem amiss and I trusted wholly that my store manager was doing things correctly. When I would conduct small internal audits, she and the pharmacists would always produce the required documentation (valid prescriptions, patient signatures, etc). I did not look further into the things going on until the investigation started. It was then that I realized what had been going on. As the owner, I felt that the correct action would be to take a plea and try to make everything right. My attorney was not good at telling me what some of the consequences would be in the long term. The investigation went on for almost two years, and I was sentenced in January of 2017.

Although there was an offer on the table, the judge and deputy attorney general decided that they should be able to argue for prison time. I was sentenced to two prison terms of 12-48months to run concurrently. I was ordered to pay $1.6 million in fees and restitution. The attorney general knew that I did not have that money, as they investigated all of my bank accounts. There was never $5million in fraud as they suggested The $5million was total sales over three years.

When I was released from prison in 2018, I spent 10 months on parole. My parole officer said that I needed to pay some restitution and fees. He also stated that the attorney general's office did not want it paid to them (it is normally paid to them to be given back to the companies that were wronged). Instead, I paid $500-$1000/month to Parole and Probation. It was a situation that my parole office had never heard of and they did not know what to do with the money paid to them. As I ended my parole, the parole office said that I was done paying and knew that it could not be paid in full. They said that the AG still did not want to have anything to do with the restitution and that their jurisdiction was done. I received a Dishonorable Discharge from parole for not being able to pay all of the fees. The Dishonorable Discharge will follow me forever. If I ever am arrested, it will be automatic jail or prison time, no probation.

I also took a plea for Medicaid Fraud and Medicaid billing was only about $30,000 over three years. I am now on the OIG watch list for 18 years because of that deal that my lawyer orchestrated. I cannot work for anyone that bills Medicare or Medicaid until I am off of that list.

The deputy AG that tried my case was also a federal prosecutor and I was threatened with federal court if I did not take a plea (due to Medicaid fraud). My attorney was also a federal defense attorney and, shortly after my release, he was appointed as a federal magistrate. His office never returned my case documents, and said that they did not think that it would matter. The majority of my paperwork was with him and is most likely destroyed. I have given the copies of what I have to you all.

I still stand by the fact that I did not commit fraud; I did not ask anyone to commit fraud; and I did not tell anyone to commit fraud. I did serve the prison time for the fraud that took place. I was denied parole after five months and ended up serving a total of 12 months in prison. I do stand by the fact that I was wrong in keeping myself as the PIC and not overseeing the day-to-day operations of my pharmacy. It has changed my life and my family's life. My family was on Medicaid for a year and is now on 90% subsidy with the Affordable Healthcare Act. If there was money anywhere, the AG would have recouped that for restitution. I took a plea because of the wrongs that happened. I take full responsibility for my actions. I made many mistakes in the two years leading up to the investigation. My lapse in judgement had cost me my career and lifetime consequences. I am applying for my license in order to continue the process of rebuilding my life and family. I do not have job prospects and will likely just do my CE to keep my license up-to-date until I am ready to continue with the pharmacy profession. I most likely will not be offered any jobs due to my OIG status, but I will work to rectify that part next.

Please do not hesitate to contact me with any other questions. ADAM

On Wed, May 12, 2021 at 1:27 PM Kristopher Mangosing <kmangosing@pharmacy.nv.gov> wrote:

Mr. Katschke,

I left you a voicemail regarding this matter as well. We are looking for proof of payment for your fines and fees. You recently sent Mark Sedar Criminal Information regarding case CR0717016. There was no Judgement and Sentence attached to that. Also, did you have any other hearings in other jurisdictions. If so we will need all documentation of those as well along with proof of payment/completion of any Orders.

Sincerely,

Kristopher Mangosing

Assistant Board Coordinator

Nevada State Board of Pharmacy

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: adam katschke [mailto:[redacted]
Sent: Wednesday, March 17, 2021 9:35 AM
To: Kristopher Mangosing <kmangosing@pharmacy.nv.gov>
Subject: Re: FW: License 15601

Thank you so much! ADAM

On Wed, Mar 17, 2021 at 8:25 AM Kristopher Mangosing <kmangosing@pharmacy.nv.gov> wrote:

Mr. Katschke,

Please submit a new application and we will place you on the next available Board meeting.

Sincerely,

Kristopher Mangosing

Assistant Board Coordinator

Nevada State Board of Pharmacy

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: adam katschke <[redacted]
Sent: Thursday, March 11, 2021 10:23 AM
To: Lisa J. Hedaria <lhedaria@pharmacy.nv.gov>
Subject: License

Hello,

My name is Adam Katschke and I surrendered my license 15601 in October of 2016. I would like to re-apply or renew my license whichever I need to do. Will you please advise me on the steps that I need to take? Thank you. ADAM

--

Adam P Katschke, PharmD
[redacted]Haystack Lane [redacted]
Caliente, NV 89008
Cell# [redacted]

--

Adam P Katschke, PharmD
[redacted]Haystack Lane [redacted]
Caliente, NV 89008
Cell# [redacted]

--

Adam P Katschke, PharmD
[redacted]Haystack Lane [redacted]
Caliente, NV 89008
Cell#[redacted]

21

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Ste 206 – Reno, NV 89521

APPLICATION BY RECIPROCATION AS A PHARMACIST

If you are requesting licensure by reciprocation (i.e. You have a current pharmacist license from another state and wish to transfer license information and only need to take the Nevada MPJE), complete this application:

Total Fee: $250.00 (Non-refundable check or credit card. Credit Cards are charged a 5% processing fee)
Made payable to: **Nevada State Board of Pharmacy**

Complete Name (no abbreviations):

First: Armin Middle: _____ Last: Aryan

Mailing Address: [redacted] S. Decatur Blvd. [redacted]

City: Las Vegas State: NV Zip Code: 89103

Telephone: [redacted] E-mail Address: [redacted]

Date of Birth: [redacted] Place of Birth: Russia

SS# or ITIN: [redacted] Sex: ☑ M or ☐ F
(Full Number Required)

Original State of Licensure you are reciprocating from must be active and issued by exam; State:
Arizona Date of Issuance: 5-31-17

College of Pharmacy Information

Graduation Date: 05-08-16 (mm/dd/yy)

Degree Received: ☑ PharmD ☐ BS in Pharmacy ☐ Other (check one)

Name of Pharmacy School: MCPHS - Worcester (Massachusetts College of pharmacy & health Sciences)

Location of School: Worcester, MA 19 Foster St, Worcester, MA 01608

If you are a **foreign graduate** you must attach a copy of your FPGEC certificate to THIS APPLICATION. You also need to complete the college of pharmacy information

Board Use Only

Processed: _____ Amount: $250 MO# 19-250346008 Entity #: _____

Email _____ MPJE _____

Other states where you are (or were) licensed as a pharmacist or print "none"

State	Lic#	Is the license Active?	State	Lic.#	Is the License Active?
AZ	5022444	Yes ☒ No ☐	~~AZ~~		Yes ☐ No ☐
		Yes ☐ No ☐			Yes ☐ No ☐

**Attach separate sheet if needed

Have you ever served in the military, either active, reserve or retired? Yes ☐ No ☒

Branch:_____
Military Occupation/Specialty:_____
Dates of Service:_____

A licensee is not required to have a Nevada State Business License, however, if you do, please provide the number: _____

	Yes	No
1. Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☒
2. Been charged, arrested or convicted of a felony or misdemeanor in any state?	☒	☐
3. Been the subject of a board citation or an administrative action or board citation whether completed or pending in any state?	☐	☒
4. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☒

If you marked YES to any of the numbered questions (1-3) above, include the following information & provide an explanation & documentation:

Board Administrative Action:	State	Date:	Case #:
		/ /	

Criminal Action:	State	Date:	Case #:	County	Court
		/ /			

FEDERALLY MANDATED REQUIREMENTS

In response to Federally mandated requirements, the Nevada Legislature and Attorney General require that we include this questions as part of all applications.

4. Are you the subject of a court order for the support of a child?.....Yes ☐ No ☒
4a. If you marked Yes, to the question 4, are you in compliance with the court order?.....Yes ☐ No ☐

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of my business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

No liability of any sort or kind shall attach to the said Nevada State Board of Pharmacy, its members, servants or employees because or by reason of the use of the authorization.

I attest to knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices.

I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacity, comes to know or has reasonable cause to believe, a child has been abused/neglected, to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Original Signature, no copies or stamps accepted

4-20-21
Date

CERTIFIED COPY

MICHAEL K. JEANES, CLERK
BY Rizzuble DEP
FILED
17 SEP 27 PM 3:00

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

STATE OF ARIZONA
VS. Plaintiff.
KAMO DANIELIAN
Defendant.

Case Number:
CR2014-158850-001

ORDER

The Court has received Defendant's Application, given proper notice and considered any response filed by the State.

IT IS ORDERED:

Applied For:	Granted	Denied	NA:	
No	☒	☐	☐	Motion for Reconsideration
Yes	Automatic pursuant to 13-912 and designated a misdemean ☒	☐	☐	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	☒	☐	☐	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	☒	☐	☐	Setting aside the judgment of guilt, dismissing the accusations or information and releasing the Defendant from all applicable penalties and disabilities resulting from the conviction.

Reason for denial:

DONE this 23 day of September, 2017

Judge of the Superior Court

HONORABLE BARBARA L. BRYNDER
MARICOPA COUNTY SUPERIOR COURT

RECEIVED FROM APPLICANT
PUBLIC DOCUMENT

RECEIVED
OCT 19 2017
SCOTTSDALE CITY COURT

CITY COURT OF SCOTTSDALE • 3700 NORTH 75th STREET • SCOTTSDALE AZ 85251

STATE OF ARIZONA, VS	01962145	TR-201502344l
Kamo Danielian		CASE NUMBER or COMPLAINT NUMBER
DEFENDANT		

APPLICATION TO SET ASIDE JUDGMENT

This Application is made in conformance with the Arizona Revised Statutes and is addressed to the Judge who pronounced sentence or imposed probation or the said Judge's successor in office

Applicant Scott A. Maasen Telephone Number [redacted]

Address [redacted] E. Vista Bonita Dr. Ste 230 City Scottsdale State AZ Zip Code 85255

Applicant is	Date of Violation/Arrest 11/22/2015	Date of Conviction 5/10/16
☐ Defendant	Offense(s) DUI - DUI. 08	Date of Birth [redacted]
☒ Attorney for Defendant	Sentence Imposed DUI 28-1381(A); 1 day jail, alcohol screening, fees & fines	

The undersigned states that the Defendant has fulfilled the conditions of probation or sentence and was discharged by the Court

Defendant in the above-captioned case, prays as follows, THAT

1 The judgment of guilt be set aside

2 The citation or complaint against the Defendant be dismissed

3 The Defendant be released from all penalties and disabilities resulting from the conviction, EXCEPT that the conviction may be pleaded and proved in any subsequent prosecution of Defendant for any offense as if the judgment of guilt had no been set aside

DATED 10/12/17

Defendant/Attorney for Defendant

AUTHORIZED _____
Defendant

ORDER

The Court, having read the foregoing Application, and in accordance with A R S § 13-907

IT IS ORDERED

☒ Granting the Application and further ordering

1 That the judgment of Defendant's guilt be set aside

2 The citation or complaint against the Defendant is dismissed

3 That the Defendant be released from all penalties and disabilities resulting from the conviction other than those imposed by A R S § 28-2207, 28-3304, 28-3306, 28-3308, 28-3319, 17-314, 17-340, as if the judgment had not been set aside

☐ Denying the Application

☐ 1 This case cannot be set aside pursuant to A R S § 13-907(D)(5)

☐ 2 All conditions of probation or sentencing have not been fulfilled

☐ 3 OTHER _____

DATED 10/26/2017

Judge

S:\All_Staff\Forms\Forms_Library\Forms_Library\Current Forms\Self Service Walk Forms - done CTAPP13UR(Rev 03/2012

PUBLIC DOCUMENT

Both cases happened more than 5 years ago, they were both set dismissed / set-aside in AZ. The State is currently in the processes of clearing all marijuana charges for individuals as it was recently legalized for recreational purposes as in this state... I have never received a marijuana card in any state & do not drink much. Both charges were Before I was licensed & before I graduated pharmacy school..

Arvind Arjan 6-20-24

Candy Nally

From: armna ry <[redacted]
Sent: Tuesday, May 4, 2021 9:17 AM
To: Candy Nally
Subject: License additional information for Armin Aryan

Here is the additional information:

1) walgreen address:

2400 E Tropicana Ave
Las Vegas, NV 89121
United States

2) the 2 main things that will come up when the background check is done are:

A) possession/sale of marijuana

B) dui

I have gotten both these set aside and dismissed off of my record. So that paperwork I sent is all I have. If I need to appear in front of the board I will.

Thank you,

Armin Aryan

E-LTP OFFICIAL APPLICATION

NABP National Association of Boards of Pharmacy

Date Completed : 4/21/2021

To : **Nevada** Board of Pharmacy

The applicant below is seeking Licensure in your State

State(s) of Examination : Arizona		**License No :**	S022444
License Being Used as the Basis of Transfer : Arizona		**Date of Issue :**	05/31/2017

APPLICANT DETAILS

e-Profile ID:	744790	**Customer ID:**	614864
Name:	Armin Aryan	**Mailing Address:**	[redacted] N Cave Creek Road Ste [redacted] Phoenix, AZ 85024
Maiden and / or Other Name(s):	Kamo Danielian	**Phone Number:**	[redacted]
Sex:	Male	**Email Address:**	[redacted]
Date of Birth:	[redacted]	**Citizenship:**	United States Citizen
SSN:	[redacted]		

PHARMACY EDUCATION

Name/Location of First Pharmacy School:	MCPHS Univ Schl of Pharm - Worcester/Worcester	**Name/Location of Additional Pharmacy School:**	
Graduation Date:	05/14/2016	**Graduation Date:**	
Degree Received:	Doctor of Pharmacy	**Degree Received:**	
Intern Hours:	2000		
EE Number:		**FPGEC Certified:** No	**FPGEC Certification Date:**

PHARMACY EXAM INFORMATION

State	Date of Exam Exam Date	NAPLEX Result	Integrated NABPLEX Result	Five-Part NABPLEX Chemistry Result	Mathematics Result	Pharmocology Result	Pharmacy Result	Practice of Pharmacy Result
AZ	3/14/2017	89						

MPJE: AZ-76

e-Profile ID : 744790 Armin Aryan Customer ID : 614864

EMPLOYMENT HISTORY

Last Three Years of Employment

Name of Employer	Address	Job Title	Start Date	End Date
Walgreens	College Station, Texas 77845	Pharmacist	11-2020	Present
The Medicine Shoppe Pharmacy	10290 N 92nd St Scottsdale, Arizona 85258	Pharmacist	03-2020	05-2020
Magellan Complete Care of AZ	15950 N 76th St Scottsdale, Arizona 85260	Pharmacist	10-2019	02-2020
Magellan Health Services	4801 E Washington St Phoenix, Arizona 85034	Pharmacist	10-2018	04-2019
Optum RX	9040 S Rita Rd Tucson, Arizona 85747	Pharmacist	10-2017	05-2018

PHARMACIST'S LICENSES

State	License Number	Exam Name	Obtained By	Issue Date	Expiration Date	Board Action	License Status
Arizona	S022444	NAPLEX	Exam	05/31/2017	10/31/2022	No	Active/Good Standing

DISCLOSURES

	Question	Answer
1.	Have you ever voluntarily surrendered your pharmacist license or any pharmacist registration issued by a federal or state controlled substance authority? If yes, provide details.	No
2.	Has your pharmacist license in any jurisdiction ever been revoked, suspended, restricted, terminated, or otherwise been subject to disciplinary action (public or private) by any board of pharmacy or other state authority? If yes, provide details.	No
3.	Are you presently under investigation or is there any disciplinary action pending against you by any licensing jurisdiction, the federal Food and Drug Administration, the federal Drug Enforcement Administration, or any state drug enforcement authority for violation of any state or federal pharmacy, liquor, or drug laws? If yes, provide details.	No
4.	Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense? If yes, provide details.	No
5.	Do you currently have any condition or impairment including, but not limited to, substance or alcohol abuse or dependency, that in any way affects your ability to practice pharmacy in a safe and competent manner? If yes, provide details.	No
6.	Have you ever had any application for initial licensure, renewal licensure, or licensure by transfer denied by any licensing authority whether in pharmacy or any other profession? If yes, provide details.	No

The National Association of Board of Pharmacy (NABP) hereby certifies that information submitted in this application has been verified under verification procedures established by NABP through the Disciplinary Clearinghouse maintained by NABP, including license and disciplinary information, which is verified through the appropriate state Board of Pharmacy or Regulatory agency

Lemrey "Al" Carter, Executive Director/Secretary

12/29

JEANES, CLERK
BY DM Maynard DEP
FILED
14 DEC 16 PM 4:22

WILLIAM G MONTGOMERY
MARICOPA COUNTY ATTORNEY

Michael G Denney
Deputy County Attorney
Bar ID #: 020429
301 West Jefferson, 7th Floor
Phoenix, AZ 85003
Telephone: (602) 372-5600
mcaoocd@mcao.maricopa.gov
MCAO Firm #: 00032000
Attorney for Plaintiff

DR 201402176128 - Phoenix Police Department
North Valley Justice Court

0131533223

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

COUNTY OF MARICOPA, RCC-DOWNTOWN

THE STATE OF ARIZONA,

Plaintiff,

vs.

KAMO DANIELIAN,

Defendant.

CR2014-158850-001

DIRECT COMPLAINT

COUNT 1: ATTEMPT TO COMMIT SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 4 FELONY (Kamo Danielian)
COUNT 2: SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 3 FELONY (Kamo Danielian)
COUNT 3: USE OF WIRE COMMUNICATION OR ELECTRONIC COMMUNICATION IN DRUG RELATED TRANSACTIONS, A CLASS 4 FELONY (Kamo Danielian)

IN CUSTODY

The complainant herein personally appears and, being duly sworn, complains on information and belief against KAMO DANIELIAN, charging that in Maricopa County, Arizona:

DCO

COUNT 1:

KAMO DANIELIAN, on or about December 13, 2014, knowingly did attempt to transport for sale, import for sale, import into this state, or offer to transport for sale or import into this state, sell, transfer or offer to sell or transfer an amount of marijuana having a weight of less than two pounds, in violation of A.R.S. §§ 13-1001, 13-3401, 13-3405, 13-3418, 13-701, 13-702, and 13-801.

COUNT 2:

KAMO DANIELIAN, on or about December 13, 2014, knowingly did transport for sale, import for sale, import into this state, or offer to transport for sale or import into this state, sell, transfer or offer to sell or transfer an amount of marijuana having a weight of less than two pounds, in violation of A.R.S. §§ 13-3401, 13-3405, 13-3418, 13-701, 13-702, and 13-801.

COUNT 3:

KAMO DANIELIAN, on or about December 13, 2014, unlawfully did use a wire communication or electronic communication to facilitate the crime of Sale of Marijuana, 13-3405, in violation of A.R.S. §§ 13-3001, 13-3417, 13-3418, 13-701, 13-702, and 13-801.

/s/ Michael G Denney
Deputy County Attorney

IN CUSTODY

#4924

Agency: Phoenix Police Department

Complainant

Subscribed and sworn upon information and belief this 16 day of December, 2014.

mgd/OK

COURT INFORMATION SHEET (CIS)

County Attorney Case No.: 0131533223

STATE v. KAMO DANIELIAN
Aliases:
Defendant's Last Known Address: **In Custody**
[redacted] East Beverly Lane
Phoenix AZ 85032

Defendant's Attorney:

DEFENDANT'S DESCRIPTION:

Race: W **Sex:** M **Hair:** BRO **Eyes:** GRN **Wgt:** 175 **Hgt:** 6'03 **DOB:** [redacted]
FBI#: [redacted] **SID#:** [redacted] **Booking#:** T138302 **Soc Sec#:** UNK

FILING STATUS:

Date Filed: _____ **Court #:** CR2014-158850-001
Court Designation: RCC-Downtown
Justice Court Precinct: North Valley Justice Court

Attorney: Michael G Denney **Bar ID:** 020429 **Location:** Downtown

CHARGES:
COUNT 1: ATTEMPT TO COMMIT SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 4 FELONY
COUNT 2: SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 3 FELONY
COUNT 3: USE OF WIRE COMMUNICATION OR ELECTRONIC COMMUNICATION IN DRUG RELATED TRANSACTIONS, A CLASS 4 FELONY

Count	ARS Literal	Date of Crime	PCN
1	13-3405A4	12/13/2014	2634109156
2	13-3405A4	12/13/2014	2634109156
3	13-3417A	12/13/2014	

DEPARTMENTAL REPORTS:
DR 201402176128 - Phoenix Police Department

Police District: Phoenix PD - Black Mountain

EXTRADITE: Arizona Only

CO-DEFENDANTS:

DWL

IN THE NORTH VALLEY JUSTICE COURT COURT
STATE OF ARIZONA, COUNTY OF MARICOPA

****FINAL**** RELEASE QUESTIONNAIRE

Notice: Unless a specific Form IV is sealed or ordered redacted by the Court, all Form IVs are public records of the Court or Clerk at the time they are provided to the Court and will be released in their entirety upon request.

DEFENDANT'S NAME KAMO DANIELIAN DOB [redacted] BOOKING NO. T138302

ALIAS(ES) CASE NO. PF2014158850001

A. GENERAL INFORMATION

Charges
1 Cts. 13-3405A4 Att. MARIJ-TRANSPORT AND/OR SELL F4
1 Cts. 13-3405A4 MARIJ-TRANSPORT AND/OR SELL F3
1 Cts. 13-3417A USE ELEC COMMUN DRUG TRANSACT F3
2 Cts. 13-3415A DRUG PARAPHERNALIA-POSSESS/USE F6

Pursuant to A.R.S. §41-1750 ten-print fingerprints were taken of the arrested person? ☒ Yes ☐ No
If yes, PCN = _____

Pursuant to A.R.S. §13-610 one or more of the above charges requires the arresting agency to secure a DNA sample from the arrested person? ☐ Yes ☒ No

If yes, does the defendant have a valid DNA sample on file with AZDPS? ☐ Yes ☐ No

If no, Arresting Agency has taken required sample? ☐ Yes ☐ No

Offense Location: 20235 N CAVE CREEK RD
Offense Date: 2014-12-13
Arrest Location: 20235 N CAVE CREEK RD PHOENIX AZ 85032
Date: 2014-12-13 Time: 21:25

B. PROBABLE CAUSE STATEMENT

1. Please summarize and include the facts which establish probable cause for the arrest:
DEFENDANT UTILIZED A SOCIAL NETWORKING WEBSITE PROFILE TO OFFER MARIJUANA FOR SALE TO AN UNDERCOVER POLICE PROFILE. DEFENDANT WAS CONTACTED BY THE MESSAGING SERVICE OF THE WEBSITE AND DEFENDANT AGREED TO SELL 28 GRAMS OF MARIJUANA FOR 200 DOLLARS. DETAILS OF THE TRANSACTION WERE NEGOTIATED BY THE DEFENDANT BY CELLULAR TELEPHONE WITH THE UNDERCOVER POLICE PROFILE. DEFENDANT AGREED TO MEET TO COMPLETE THE TRANSACTION AT THE SHOPPING ENTER AT 20235 NORTH CAVE CREEK ROAD. DEFENDANT ARRIVED WITH THE MARIJUANA AND COMMUNICATED TO THE POLICE PROFILE THAT HE WAS IN A SILVER MERCEDES. POLICE CONTACTED DEPENDANT IN HIS SILVER MERCEDES WHICH WAS PARKED IN THE PARKING LOT. WHEN DEFENDANT WAS CONTACTED THE STRONG AROMA OF MARIJUANA WAS DETECTED AND THE DEFENDANT WAS TOLD TO EXIT THE VEHICLE AND HE ADMITTED HE WAS IN POSSESSION OF MARIJUANA. THE MARIJUANA WAS ON THE FLOORBOARD OF DEFENDANTS VEHICLE ALONG WITH ONE ELECTRONIC SCALE. AN ADDITIONAL CALE WAS LOCATED NEAR THE FRONT PASSENGER SEAT. DEFENDANT WAS ALSO IN POSSESSION OF THE CELLULAR TELEPHONE USED TO NEGOTIATE THE TRANSACTION. POLICE VERIFIED THE TELEPHONE WAS THE CORRECT PHONE FOR THE TRANSACTION BY PLACING A CALL TO THE CELLULAR TELEPHONE. DEFENDANT REFUSED TO BE INTERVIEWED REGARDING THE OFFENSE. DEFENDANT WAS BOOKED.

FIELD TEST - POSITIVE FOR MARIJUANA
DUA

C. OTHER INFORMATION (Check if applicable)

1. ☐ Defendant is presently on probation, parole or any other form of release involving other charges or convictions:
Explain:

2. List any prior:
Arrests?

Convictions?

F.T.A.'s?

3. Is there any indication the defendant is:
☐ An Alcoholic? ☐ An Addict?
☐ Mentally disturbed? ☐ Physically Ill?

4. ☐ Defendant is currently employed
With whom

How long:

5. Where does the defendant currently reside? 2621 EAST BEVERLY LANE PHOENIX, AZ 85032
With whom REFUSED INFO
How long: 1 years _____ months _____ days

6. What facts indicate the defendant will flee if released?
Explain: DEFENDANT SAYS HE IS A REGISTERED PHARMACY STUDENT IN MASSACHUSSETTS AND MAY LEAVE AZ

7. What facts does the state have to oppose an unsecured release? Explain: DEFENDANT IS A FLIGHT RISK BECAUSE HE SAYS HE IS REGISTERED AS A STUDENT IN MASSACHUSSETTS

D. CIRCUMSTANCES OF THE OFFENSE(Check if applicable)

1. ☐ Firearm or other weapon was used
Type:

☐ Someone was injured by the defendant

☐ Medical attention was necessary

Nature of injuries: N/A

2. ☐ Someone was threatened by the defendant
Nature and extent of threats:

3. If property offense, value of property taken or damaged:

☐ Property was recovered
4. Name(s) of co-defendant(s):

DEFENDANT'S NAME KAMO DANIELIAN DOB [redacted] BOOKING NO. T138302

CASE NO. PF2014158850001 Page 2 of 2

E. CRIMES OF VIOLENCE

1. Relationship of defendant to victim:

☐ Victim(s) and defendant reside together

2. How was the situation brought to the attention of the police?
☐ Victim ☐ Third Party ☐ Officer observed

3. ☐ There are previous incidents involving these same parties
Explain:

4. Is defendant currently the subject of:
☐ An order of protection ☐ Any other court order
☐ Injunction against harassment
Explain:

F. DOMESTIC VIOLENCE ISSUES (Check if applicable)

Defendant's actions

☐ Threats of homicide/suicide/bodily harm
☐ Control/ownership/jealousy issues ☐ Crime occurs in public
☐ Prior history of DV ☐ Kidnapping
☐ Frequency/intensity of DV increasing ☐ Depression
☐ Access to or use of weapons ☐ Stalking behavior
☐ Violence against children/animals
☐ Multiple violations of court orders

G. CIRCUMSTANCES OF THE ARREST (Check if applicable)

1. Did the defendant attempt to:

☐ Avoid arrest ☐ Resist arrest ☐ Self Surrender

Explain:

N/A

2. ☒ Defendant was armed when arrested
Type: DEFENDANT HAD A BB GUN APPEARIG TO BE A BERETA STYLE SEMI AUTO PISTOL

3. ☒ Evidence of the offense was found in the defendant's possession
Explain: SEVERAL CONTAINERS WITH MARIJUANA, 2 DRUG WEIGHING SCALES, AND CELLULAR PHONE USED TO CONDUCT TRANSACTION

4. Was the defendant under the influence of alcohol or drugs at the time of the offense?
☐ Yes ☒ No ☐ Unk

H. DRUG OFFENSES

1. If the defendant is considered to be a drug dealer, please state the supporting facts: DEFENDANT OFFERED MARIJUANA FOR SALE AND AGREED TO SELL 22 GRAMS OF MARIJUANA TO POLICE FOR $200

2. What quantities and types of illegal drugs are directly involved in the offense? MARIJUANA APPROXIMATELY 20 GRAMS ESTIMATED

☒ Drug field test completed

☒ Defendant admission of drug type
Approximate monetary value: $200 DOLLARS

3. Was any money seized?
☐ Yes ☒ No
Amount: $

I. ADDITIONAL INFORMATION

1. Military Service:

Has the defendant served in the military services of the United States? ☐ Yes ☒ No ☐ Unknown

If yes, currently on active duty? ☐ Yes ☐ No

Branches Served In: ____ ____ ____
(AF - Air Force AR - Army CG - Coast Guard MC - Marine Corp MM - Merchant Marines NG - National Guard NV - Navy RS - Reserves)

2. Is the defendant homeless?
☐ Yes ☒ No ☐ Unknown

JUDICIAL OFFICER REVIEW OF PROBABLE CAUSE STATEMENT AND COMPLAINT ON OATH OR AFFIRMATION

☐ Complaint Review
☐ Witness sworn
☐ Reviewed Form IV
☐ Other sources:
☐ PC determined

Judicial Officer

Pursuant to AO 2003-046, the oath has been administered pursuant to the law and required procedures. AD

"If a fugitive arrest, a Form IVA must also be completed"

I certify that the information presented is true to the best of my knowledge.

MEELHUYSEN, MICHAEL/7090	AZ0072300/602-495-5008	2014-12-13
ARRESTING OFFICER/SERIAL NUMBER	ARREST AGENCY/DUTY PHONE NUMBER	DATE

201402176128/AZ0072300	/	/
DEPARTMENTAL REPORT NO.	DEPARTMENTAL REPORT NO.	DEPARTMENTAL REPORT NO.

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
I. OSUNA, Deputy
12/16/2014 3:45:00 PM
Filing ID 6294576

SUPERIOR COURT OF ARIZONA FOR
Maricopa County
Final Release Order and Order Regarding Counsel

State of Arizona	1 Cnt MARIJ-TRANSPORT F3	2 Cnt DRUG PARAPHERNA F6	CaseNumber: PF2014158850001
	1 Cnt USE ELEC COMMUN F4	1 Cnt Att.MARIJ-TRANSPORT F4	
vs.			Booking#: T138302
Kamo Danielian			

It is hereby ordered that **Kamo Danielian shall be released** as indicated and must comply with ALL release conditions.

NEXT HEARINGS

Status Conference	December 29, 2014 at 08:30 AM at South Court Tower, 175 W. Madison Street, 3rd Floor, Phoenix, AZ, 85003-2243 Courtroom: 3B **Docket: RCCT3**
Preliminary Hearing	January 02, 2015 at 08:30 AM at South Court Tower, 175 W. Madison Street, 3rd Floor, Phoenix, AZ, 85003-2243 Courtroom: 3B **Docket: RCCT3**

WARNING: If the defendant appears at the next hearing without a lawyer, the hearing may still proceed as scheduled.

RELEASE TYPE

Bailable As a Matter of Right

The defendant has been found to be bailable as a matter of right. IT IS HEREBY ORDERED that the defendant must comply with all release conditions and shall be released from custody in this Cause Number as follows:

Release Own Recognizance

The defendant is released without any condition of an undertaking relating to, or deposit of security, and promises to appear in Court as required.

RELEASE CONDITIONS

1. You are not to initiate contact with the arresting officers.
2. You are not to possess any drugs without a valid prescription.
3. You are not to drive a motor vehicle without a valid driver's license.
4. You must continue to provide the court with proof of your local address.

You must appear at all court proceedings in this case or your release conditions can be revoked, a warrant will be issued and proceedings may go forward in your absence. In addition, failure to appear at a future court proceeding may result in a waiver of any claim that you were not informed of a plea offer made in your case by the State. a.You will appear to answer and submit to all further orders and processes of the court having jurisdiction of the case. b.You will refrain from committing any criminal offenses.c.You will diligently prosecute any appeal. d.You will not leave the state without permission of the court.
If you violate any conditions of this release order, the court may order the bond and any security deposited in connection therewith forfeited to the State of Arizona. In addition, the court may issue a warrant for your arrest upon learning of your violation of any conditions of your release. After a hearing, if the court finds that you have not complied with the conditions of release, it may modify the conditions or revoke your release altogether.

ATTORNEY APPOINTMENT

The Court finds you to be indigent and orders an attorney to provide you representation.
You must contact the Office of the Maricopa County Public Defender at **620 W Jackson Street, Suite 4015, Phoenix, AZ. 602-506-7711**

ACKNOWLEDGEMENT BY DEFENDANT

I have received a copy of this form. I understand the standard conditions, all other conditions, and the consequences of violating this release order. I agree to comply fully with each of the conditions imposed on my release and to notify the court promptly in the event I change my place of residence.

Date 12/14/2014 8:00:00 AM

Lisa Roberts

Lisa M Roberts
Judge / Commissioner

Address: 2621 EAST BEVERLY LANE

City, State, Zip: PHOENIX, AZ, 85032

Signature: Kamo Danielian

Kamo Danielian
Defendant

IN THE NORTH VALLEY JUSTICE COURT COURT
STATE OF ARIZONA, COUNTY OF MARICOPA

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
R. Krane, Deputy
12/16/2014 3:45:00 PM
Filing ID 6294572

****FINAL****

RELEASE QUESTIONNAIRE

Notice: Unless a specific Form IV is sealed or ordered redacted by the Court, all Form IVs are public records of the Court or Clerk at the time they are provided to the Court and will be released in their entirety upon request.

DEFENDANT'S NAME KAMO DANIELIAN DOB [redacted] BOOKING NO. T138302

ALIAS(ES) CASE NO. PF2014158850001

A. GENERAL INFORMATION

Charges
1 Cts. 13-3405A4 Att. MARIJ-TRANSPORT AND/OR SELL F4
1 Cts. 13-3405A4 MARIJ-TRANSPORT AND/OR SELL F3
1 Cts. 13-3417A USE ELEC COMMUN DRUG TRANSACT F3
2 Cts. 13-3415A DRUG PARAPHERNALIA-POSSESS/USE F6

Pursuant to A.R.S. §41-1750 ten-print fingerprints were taken of the arrested person? ☒ Yes ☐ No
If yes, PCN = _____

Pursuant to A.R.S. §13-610 one or more of the above charges requires the arresting agency to secure a DNA sample from the arrested person? ☐ Yes ☒ No

If yes, does the defendant have a valid DNA sample on file with AZDPS? ☐ Yes ☐ No

If no, Arresting Agency has taken required sample? ☐ Yes ☐ No

Offense Location: 20235 N CAVE CREEK RD
Offense Date: 2014-12-13
Arrest Location: 20235 N CAVE CREEK RD PHOENIX AZ 85032
Date: 2014-12-13 Time: 21:25

B. PROBABLE CAUSE STATEMENT

1. Please summerize and include the facts which establish probable cause for the arrest:
DEFENDANT UTILIZED A SOCIAL NETWORKING WEBSITE PROFILE TO OFFER MARIJUANA FOR SALE TO AN UNDERCOVER POLICE PROFILE. DEFENDANT WAS CONTACTED BY THE MESSAGING SERVICE OF THE WEBSITE AND DEFENDANT AGREED TO SELL 22 GRAMS OF MARIJUANA FOR 200 DOLLARS. DETAILS OF THE TRANSACTION WERE NEGOTIATED BY THE DEFENDANT BY CELLULAR TELEPHONE WITH THE UNDERCOVER POLICE PROFILE. DEFENDANT AGREED TO MEET TO COMPLETE THE TRANSACTION AT THE SHOPPING ENTER AT 20235 NORTH CAVE CREEK ROAD. DEFENDANT ARRIVED WITH THE MARIJUANA AND COMMUNICATED TO THE POLICE PROFILE THAT HE WAS IN A SILVER MERCEDES. POLICE CONTACTED DEFENDANT IN HIS SILVER MERCEDES WHICH WAS PARKED IN THE PARKING LOT. WHEN DEFENDANT WAS CONTACTED THE STRONG AROMA OF MARIJUANA WAS DETECTED AND THE DEFENDANT WAS TOLD TO EXIT THE VEHICLE AND HE ADMITTED HE WAS IN POSSESSION OF MARIJUANA. THE MARIJUANA WAS ON THE FLOORBOARD OF DEFENDANTS VEHICLE ALONG WITH ONE ELECTRONIC SCALE. AN ADDITIONAL CALE WAS LOCATED NEAR THE FRONT PASSENGER SEAT. DEFENDANT WAS ALSO IN POSSESSION OF THE CELLULAR TELEPHONE USED TO NEGOTIATE THE TRANSACTION. POLICE VERIFIED THE TELEPHONE WAS THE CORRECT PHONE FOR THE TRANSACTION BY PLACING A CALL TO THE CELLULAR TELEPHONE. DEFENDANT REFUSED TO BE INTERVIEWED REGARDING THE OFFENSE. DEFENDANT WAS BOOKED.

C. OTHER INFORMATION (Check if applicable)

1. ☐ Defendant is presently on probation, parole or any other form of release involving other charges or convictions:
Explain:

2. List any prior:
Arrests?

Convictions?

F.T.A.'s?

3. Is there any indication the defendant is:
☐ An Alcoholic? ☐ An Addict?
☐ Mentally disturbed? ☐ Physically Ill?

4. ☐ Defendant is currently employed
With whom

How long:

5. Where does the defendant currently reside? 2621 EAST BEVERLY LANE PHOENIX, AZ 85032
With whom REFUSED INFO
How long: 1 years _____ months _____ days

6. What facts indicate the defendant will flee if released?
Explain: DEFENDANT SAYS HE IS A REGISTERED PHARMACY STUDENT IN MASSACHUSSETTS AND MAY LEAVE AZ

7. What facts does the state have to oppose an unsecured release? Explain:DEFENDANT IS A FLIGHT RISK BECAUSE HE SAYS HE IS REGISTERED AS A STUDENT IN MASSACHUSSETTS

D. CIRCUMSTANCES OF THE OFFENSE(Check if applicable)

1. ☐ Firearm or other weapon was used
Type:

☐ Someone was injured by the defendant

☐ Medical attention wes necessary

Nature of injuries: N/A

2. ☐ Someone was threatened by the defendant
Nature and extent of threats:

3. If property offense, value of property taken or damaged:

☐ Property was recovered
4. Name(s) of co-defendant(s):

DEFENDANT'S NAME KAMO DANIELIAN DOB [redacted] BOOKING NO. T138302

CASE NO. PF2014158850001 Page 2 of 2

E. CRIMES OF VIOLENCE

1. Relationship of defendant to victim:

☐ Victim(s) and defendant reside together

2. How was the situation brought to the attention of the police?
☐ Victim ☐ Third Party ☐ Officer observed

3. ☐ There are previous incidents involving these same parties
Explain:

4. Is defendant currently the subject of:
☐ An order of protection ☐ Any other court order

☐ Injunction against harassment

Explain:

F. DOMESTIC VIOLENCE ISSUES (Check if applicable)

Defendant's actions

☐ Threats of homicide/suicide/bodily harm

☐ Control/ownership/jealousy issues ☐ Crime occurs in public

☐ Prior history of DV ☐ Kidnapping

☐ Frequency/intensity of DV increasing ☐ Depression

☐ Access to or use of weapons ☐ Stalking behavior

☐ Violence against children/animals

☐ Multiple violations of court orders

G. CIRCUMSTANCES OF THE ARREST (Check if applicable)

1. Did the defendant attempt to:

☐ Avoid arrest ☐ Resist arrest ☐ Self Surrender

Explain:

N/A

2. ☒ Defendant was armed when arrested
Type: DEFENDANT HAD A BB GUN APPEARIG TO BE A BERRETA STYLE SEMI AUTO PISTOL

3. ☒ Evidence of the offense was found in the defendant's possession
Explain: SEVERAL CONTAINERS WITH MARIJUANA, 2 DRUG WEIGHING SCALES, AND CELLULAR PHONE USED TO CONDUCT TRANSACTION

4. Was the defendant under the influence of alcohol or drugs at the time of the offense?
☐ Yes ☒ No ☐ Unk

H. DRUG OFFENSES

1. If the defendant is considered to be a drug dealer, please state the supporting facts: DEFENDANT OFFERED MARIJUANA FOR SALE AND AGREED TO SELL 22 GRAMS OF MARIJUANA TO POLICE FOR $200

2. What quantities and types of illegal drugs are directly involved in the offense? MARIJUANA APPROXIMATELY 20 GRAMS ESTIMATED

☒ Drug field test completed

☒ Defendant admission of drug type
Approximate monetary value: $200 DOLLARS

3. Was any money seized?

☐ Yes ☒ No
Amount: $

I. ADDITIONAL INFORMATION

1. Military Service:

Has the defendant served in the military services of the United States? ☐ Yes ☒ No ☐ Unknown

If yes, currently on active duty? ☐ Yes ☐ No

Branches Served In: ____ ____ ____
(AF - Air Force AR - Army CG - Coast Guard MC - Marine Corp MM - Merchant Marines NG - National Guard NV - Navy RS - Reserves)

2. Is the defendant homeless?
☐ Yes ☒ No ☐ Unknown

"If a fugitive arrest, a Form IVA must also be completed"

I certify that the information presented is true to the best of my knowledge.

MEELHUYSEN, MICHAEL/7090	AZ0072300/602-495-5008	2014-12-13
ARRESTING OFFICER/SERIAL NUMBER	ARREST AGENCY/DUTY PHONE NUMBER	DATE
201402176128/AZ0072300	/	/
DEPARTMENTAL REPORT NO.	DEPARTMENTAL REPORT NO.	DEPARTMENTAL REPORT NO.

PRETRIAL SERVICES AGENCY REPORT

State of Arizona vs. KAMO DANIELIAN
Booking #: T138302

Reviewed By: Kathleen Marie Defrees
IA Type: Superior Court New Case
Interview Type: Full

Superior Court of Arizona, at 05:50 AM on 12/14/2014

SUMMARY

Final Risk Score:	11	Interview Refused/Unfit:	No
Final Risk Level:	1	Prior FTA:	None
Highest Severity ARS Code:	13-3405A4 MARIJ-TRANSPORT AND/OR SELL	Prior Felony Convictions:	None
Class Felony:	F3	Resides Alone:	SALVA DANIELAIN
Indigence Selection:	Defendant is indigent	Weapons Used:	No
		Injury to Victim:	No

Open Cases: Case# : None

NOTES AND OTHER INFORMATION

Holds:

None

Statuses:

Substance Abuse Interpreter Yes

Notes: no fbi or sid available

no juvy hx located

RECOMMENDATIONS

Recommendation Level: Release Own Recognizance

Special Conditions:

Additional Recommendations:

Contact

You are not to initiate contact with the arresting officers

Prohibitions

You are not to possess any drugs without a valid prescription
You are not to drive a motor vehicle without a valid driver's license

Requirements

You must continue to provide the court with proof of your local address

PRETRIAL SERVICES AGENCY
FINANCIAL INFORMATION

Defendant's Name: KAMO DANIELIAN Booking #: T138302

The Judicial Officer needs to know about your financial situation in determining whether to require you to post bond and, if so, the amount of bond. The Judicial Officer must also determine if you are entitled to have a lawyer appointed to represent you.

Number of Dependents:	1		
Employment/Student/Caregiver Status:	Employed/Full Time		
Employment Verified:	No	Occupation :	LOT ATTENDANT
Employment Status:	Current	Length of Employment :	3 Months
Employer Name:	EARNHART AUTO		

Income (Monthly):		Expense (Monthly):	
Pay Amount:		Rent / Home Payment:	$0.00
Payroll Deductions for Savings, Stocks, etc.:	$0.00	Utilities:	$0.00
Spouse Income:	$0.00	Food:	$0.00
Public Assistance/Food Stamps:	$16.00	Gas:	$0.00
Disability Benefits:	$0.00	Cell Phone:	$0.00
Veteran Benefits:	$0.00	Cable:	$0.00
Social Security Benefits:	$0.00	Charge Account Payments:	$0.00
Accident Benefits:	$0.00	Loan Payments:	$0.00
Retirement Benefits:	$0.00	Car Loan Payments:	$0.00
Allotment Checks(Tribal):	$0.00	Car Insurance:	$0.00
Interest:	$0.00	Child Support:	$0.00
Dividends:	$0.00	Medical Care:	$0.00
Child Support Received:	$0.00	Court Fines and Fees:	$0.00
Alimony Or Maintenance Received:	$0.00	Alimony:	$0.00
Unemployment Benefits:	$0.00	Child Care:	$0.00
Other Income: NONE	$0.00	Union Dues:	$0.00
Net Income:	$1,216.00	Other Expense: MISC	$600.00
		Delinquent Expense: NONE	$0.00
		Total Expenses:	$600.00

Asset:		Asset (Continued):	
Cash Asset:	$0.00	Stereos:	$0.00
Checking Amount:	$0.00	Televisions:	$0.00
Savings Amount:	$0.00	Musical Instruments:	$0.00
Cash Owed To This Person:	$0.00	Stock In Trade:	$0.00
Cash Value Of Stock Or Bonds:		Tools:	$0.00
Value: $0.00 Owed: $0.00 Net:	$0.00	Jewelry:	$0.00
Real Estate Location: NONE		Jail Property:	$0.00
Value: $0.00 Owed: $0.00 Net:	$0.00	Other Assets:	$0.00
Automobile 1: NONE		**Total Assests:**	$0.00
Value: $0.00 Owed: $0.00 Net:	$0.00		
Automobile 2: NONE			
Value: $0.00 Owed: $0.00 Net:	$0.00		
Trailer: NONE			
Value: $0.00 Owed: $0.00 Net:	$0.00		
Boat: NONE			
Value: $0.00 Owed: $0.00 Net:	$0.00		

PRETRIAL SERVICES AGENCY
FINANCIAL INFORMATION

Defendant's Name: KAMO DANIELIAN Booking #: T138302

The Judicial Officer needs to know about your financial situation in determining whether to require you to post bond and, if so, the amount of bond. The Judicial Officer must also determine if you are entitled to have a lawyer appointed to represent you.

Number of Dependents:	1		
Employment/Student/Caregiver Status:	Employed/Full Time		
Employment Verified:	No	Occupation :	LOT ATTENDANT
Employment Status:	Current	Length of Employment :	3 Months
Employer Name:	EARNHART AUTO		

Acknowledgement by Defendant

OATH UNDER PENALTY OF PERJURY: I have truthfully given the information, which appears in this statement. I have not concealed, or in any way misrepresented my financial resources. I am aware that I can be held in contempt of court or prosecuted for perjury, if I made any false statements. If the Public Defender or a court appointed attorney accepts my case, I will notify them of any changes in financial resources, employment, income or re-arrest. I also give permission for the Pretrial Services Agency staff to contact anyone named above or any agency or business concerning their investigation into the statement I made. I hereby make these statements under oath.

Kamo Danielian

KAMO DANIELIAN

STATE OF ARIZONA, COUNTY OF MARICOPA
RELEASE QUESTIONNAIRE SUPPLEMENTAL - PROP 100 QUESTIONS



Bk#: T138302
DANIELIAN, KAMO
Bk Dt: 12/14/2014



BOOKING NO _____

CASE NO. _____

1. Is the alleged offense a class 1, 2, 3, or 4 felony or a violation of A.R.S. 28-1383?

☒ YES ☐ NO ☐ UNKNOWN

If yes, as to guilt, proof is evident or presumption is great for the following reasons. Explain in detail (e.g., arresting officer or other law enforcement officers witnessed offense, physical evidence directly connects defendant to offense, multiple eyewitnesses, defendant admissions, victim statements, nature of injuries, incriminating photographic, audio, visual or computer evidence, defendant attempted to flee or resist arrest).

SEE ATTACHED

2. Has the person entered or remained in the United States illegally?

☐ YES ☒ NO ☐ UNKNOWN

If yes, probable cause is established for the following reasons. Explain in detail (e.g., admission of the person, statements of codefendants at the time of arrest, verification of illegal presence, information provided at the issuance of a warrant in conjunction with a direct complaint or grand jury proceeding establishes illegal presence).

I certify that the information presented is true to the best of my knowledge.

MEELHUISEN 7090
ARRESTING OFFICER / SERIAL NUMBER

PHX 602-495-5058
ARREST AGENCY / DUTY PHONE NUMBER

12/13/14
DATE

FOI
CtP

OEN

IN THE SUPERIOR COURT
STATE OF ARIZONA - MARICOPA COUNTY

For Clerk's Use Only
FILED
12/29/14 3:28pm
MICHAEL K JEANES, Clerk
By K. Hill Deputy

STATE OF ARIZONA
VS

CASE NUMBER: CR2014-158850-001 DT

MOTION TO:

- [X] Continue 1/12 SC
- [ ] Dismiss 1/15 EVPH
- [ ] Modify Release Conditions [ ] OR [ ] Pretrial Services [ ] 3rd party
- [ ] Other _____

Kamo Danielian
Defendant

[ ] ORAL ARGUMENT REQUESTED [X] ORAL ARGUMENT NOT REQUESTED

Reason for Motion: To gather further information, Time waived.

Date: 12/29/14 _____ #022472
[ ] Prosecutor [X] Defense Attorney [ ] Defendant Bar #

[ ] Objection to the above Motion for the following reasons:
[X] Does not Object to the Motion Above So long as time is waived.

Date: 12/29/14 _____ 050045
[X] Prosecutor [ ] Defense Attorney [ ] Defendant Bar #

ORDER

[ ] IT IS HEREBY ORDERED DENYING THE MOTION

[X] IT IS HEREBY ORDERED GRANTING THE MOTION

This case is reset to: Date: 1/12/15 1/15/15 Time: 8:30

[X] This is a [X] Witness (1/15/15) or [X] non-witness (1/12/15) setting. [ ] Defendant agrees to straight waive or plead.

[X] Time is Ordered excluded [ ] not excluded pursuant to Rule 8, AZ Criminal Rules.

JUDGE: _____ DATE: 12/29/14

8000-002 R11-11

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
01/02/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT

12/29/2014

COMMISSIONER CHARLES DONOFRIO III
FOR COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
K. Miller
Deputy

STATE OF ARIZONA

BENJAMIN L TATE

v.

KAMO DANIELIAN (001)

CCC PUBLIC DEFENDER-

CONTINUANCE

Upon written motion by counsel for the Defense, and good cause appearing based on the following grounds:

Attempting to settle,

THE COURT FINDS extraordinary circumstances exist and that a delay is indispensable to the interests of justice.

The Defendant having waived the applicable time limits,

IT IS ORDERED granting the Motion for Continuance.

IT IS FURTHER ORDERED continuing Status Conference from 12/29/2014 to 1/12/2015 at 8:30 a.m. before Commissioner Rummage.

IT IS FURTHER ORDERED continuing Preliminary Hearing from 1/2/2015 to 1/15/2015 at 8:30 a.m. before Commissioner Rummage.

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT 12/29/2014

IT IS FURTHER ORDERED excluding all time from 12/29/2014 through 1/12/2015 (14 days). NEW LAST DAY: 7/15/2015.

IT IS FURTHER ORDERED affirming prior release orders.

41

Ben

Rummage

IN THE SUPERIOR COURT
STATE OF ARIZONA - MARICOPA COUNTY

For Clerk's Use Only

FILED
11/12/15 1:25pm
MICHAEL K. JEANES, Clerk
By A. Callahan
A. Callahan, Deputy

STATE OF ARIZONA
VS

CASE NUMBER: CR2014-158850-001

MOTION TO:

- [X] Continue SC - 1/26
- [ ] Dismiss PH - 1/30
- [ ] Modify Release Conditions [ ] OR [ ] Pretrial Services [ ] 3rd party
- [ ] Other

Kamo Danielian
Defendant

[ ] ORAL ARGUMENT REQUESTED [X] ORAL ARGUMENT NOT REQUESTED

Reason for Motion: The defense requests a Continuance to allow defense Counsel to submit a deviation request. The defendant agrees to waive time.

Date: 11/12/15 [signature] 028847
[ ] Prosecutor [X] Defense Attorney [ ] Defendant Bar #

[ ] Objection to the above Motion for the following reasons:
[X] Does not Object to the Motion Above So long as time D waived.

Date: 1/12/15 [signature] 030042
[X] Prosecutor [ ] Defense Attorney [ ] Defendant Bar #

ORDER

[ ] IT IS HEREBY ORDERED DENYING THE MOTION

[X] IT IS HEREBY ORDERED GRANTING THE MOTION

This case is reset to: Date: 1/28 1/30 Time: 8:30

[ ] This is a [ ] Witness or [ ] non-witness setting. [ ] Defendant agrees to straight waive or plead.

[X] Time is ordered excluded [ ] not excluded pursuant to Rule 8, AZ Criminal Rules.

JUDGE: [signature] DATE: 11/12/15

Commissioner James Rummage

8000-002 R11-11

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
01/13/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT

01/12/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
A. Callahan
Deputy

STATE OF ARIZONA

BENJAMIN L TATE

v.

KAMO DANIELIAN (001)

KRISTI SETZER

MINUTE ENTRY

Upon stipulation of counsel, and good cause appearing;

IT IS ORDERED continuing the Status Conference in the above-entitled cause number to 01/26/2015 at 8:30 a.m. in this division.

IT IS FURTHER ORDERED continuing the Preliminary Hearing in the above-entitled cause number to 01/30/2015 at 8:30 a.m. in this division.

IT IS FURTHER ORDERED excluding time.

LR

Rummage

Per

IN THE SUPERIOR COURT
STATE OF ARIZONA - MARICOPA COUNTY

For Clerk's Use Only

FILED 1/26/2015 4:30 PM
MICHAEL K. JEANES, Clerk
By [illegible] Deputy

STATE OF ARIZONA
VS

CASE NUMBER: CR2014-158850-001

MOTION TO:

☒ Continue SC - 2/2

☐ Dismiss PH - 2/6

☐ Modify Release Conditions ☐ OR ☐ Pretrial Services ☐ 3rd party

☐ Other _____

Kamo Danielian
Defendant

☐ ORAL ARGUMENT REQUESTED ☒ ORAL ARGUMENT NOT REQUESTED

Reason for Motion: Mr. Danielian is interested in accepting the state's offer but more time is needed to enter the plea. Defense agrees to waive time.

Date: 1/26/15 [signature] 028847

☐ Prosecutor ☒ Defense Attorney ☐ Defendant Bar #

☐ Objection to the above Motion for the following reasons: So long as time is waived.
☒ Does not Object to the Motion Above

Date: 1/26/15 [signature] 030095

☒ Prosecutor ☐ Defense Attorney ☐ Defendant Bar #

ORDER

☐ IT IS HEREBY ORDERED DENYING THE MOTION

☑ IT IS HEREBY ORDERED GRANTING THE MOTION

This case is reset to: Date: 2/2 2/6 Time: 8:30

☐ This is a ☐ Witness or ☐ non-witness setting. ☐ Defendant agrees to straight waive or plead.

☑ Time is Ordered excluded ☐ not excluded pursuant to Rule 8, AZ Criminal Rules.

JUDGE: [signature] DATE: 1/26/15

Commissioner James Rummage

8000-002 REV-11

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
01/30/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT

01/26/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
S. Cornfield/K. Sotello-Stevenson
Deputy

STATE OF ARIZONA

BENJAMIN L TATE

v.

KAMO DANIELIAN (001)

KRISTI SETZER

CONTINUANCE

The Court having received and considered the Motion to Continue filed by Defense Counsel in this cause number, and good cause appearing;

IT IS ORDERED continuing the Status Conference in this cause number to 02/02/2015 at 8:30 a.m. in the Downtown Regional Court Center.

IT IS ORDERED continuing the Preliminary Hearing in this cause number to 02/06/2015 at 8:30 a.m. in the Downtown Regional Court Center.

IT IS FURTHER ORDERED excluding time.

WILLIAM G MONTGOMERY
MARICOPA COUNTY ATTORNEY
Bar ID #: 021246
301 West Jefferson, 8th Floor
Phoenix, AZ 85003
Telephone: (602) 506-8102
mcaoocd@mcao.maricopa.gov
MCAO Firm #: 00032000
Attorney for Plaintiff

FILED
2/02/2015 3:39pm
MICHAEL K. JEANES, Clerk
By [signature]
Deputy

DR 201402176128 - Phoenix Police Department
0131533223

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

COUNTY OF MARICOPA

THE STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	CR2014-158850-001 DT INFORMATION **COUNT 1:** ATTEMPT TO COMMIT SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 4 FELONY (KAMO DANIELIAN) **COUNT 2:** SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 3 FELONY (KAMO DANIELIAN) **COUNT 3:** USE OF WIRE COMMUNICATION OR ELECTRONIC COMMUNICATION IN DRUG RELATED TRANSACTIONS, A CLASS 4 FELONY (KAMO DANIELIAN)

THE MARICOPA COUNTY ATTORNEY accuses KAMO DANIELIAN, on this date, charging that in Maricopa County, Arizona:

COUNT 1:

KAMO DANIELIAN, on or about December 13, 2014, knowingly did attempt to transport for sale, import for sale, import into this state, or offer to transport for sale or import into this state, sell, transfer or offer to sell or transfer an amount of marijuana having a weight of less than

two pounds, in violation of A.R.S. §§ 13-1001, 13-3401, 13-3405, 13-3418, 13-701, 13-702, and 13-801.

COUNT 2:

KAMO DANIELIAN, on or about December 13, 2014, knowingly did transport for sale, import for sale, import into this state, or offer to transport for sale or import into this state, sell, transfer or offer to sell or transfer an amount of marijuana having a weight of less than two pounds, in violation of A.R.S. §§ 13-3401, 13-3405, 13-3418, 13-701, 13-702, and 13-801.

COUNT 3:

KAMO DANIELIAN, on or about December 13, 2014, unlawfully did use a wire communication or electronic communication to facilitate the crime of Sale of Marijuana, 13-3405, in violation of A.R.S. §§ 13-3001, 13-3417, 13-3418, 13-701, 13-702, and 13-801.

Dated February 2, 2015.

WILLIAM G MONTGOMERY
MARICOPA COUNTY ATTORNEY

BY: _____
Deputy County Attorney for
Maricopa County Attorney William G Montgomery

mgd

1:50 pm

2/02/2015 3:39 PM
FILED
MICHAEL K. JEANES, Clerk
By [illegible]
Deputy

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, DOB: [redacted] Booking #: T138302, Defendant.	)	CR2014-158850-001 WAIVER OF PRELIMINARY HEARING WITH PLEA AGREEMENT

DECLARATION by defendant as follows.
Defendant is represented by Kristin Setzer

KD I hereby voluntarily waive my right to a preliminary hearing understanding that I will be held to answer and an information will be filed charging me with having committed.

COUNT 1: ATTEMPT TO COMMIT SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 4 FELONY (KAMO DANIELIAN)
COUNT 2: SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 3 FELONY (KAMO DANIELIAN)
COUNT 3: USE OF WIRE COMMUNICATION OR ELECTRONIC COMMUNICATION IN DRUG RELATED TRANSACTIONS, A CLASS 4 FELONY (KAMO DANIELIAN)

All committed on December 13, 2014

This is a non-dangerous, non-repetitive offense under the criminal code.

KD I understand and acknowledge that:
A. I have e right to a preliminary hearing.
B. I am represented by an attorney now. Further, I know I have a right to an attorney for all further proceedings in this case. If I cannot afford one, then one will be appointed to represent me at this preliminary hearing as well as in the Superior Court for all purposes including trial, free of charge.
C. I am giving up the right to confront and cross-examine witnesses.
D. I am giving up the right to present evidence in my behalf and that I am giving up the right to have the magistrate determine if there is sufficient evidence against me to establish probable cause to hold me to answer in the Superior Court on the above stated charges, as well as the right to a dismissal of charges against me if the evidence is insufficient.

The State of Arizone and the Defendant hereby agree to the following disposition of this case:

Plea: The Defendant agrees to plead **GUILTY** to:

Count 1: (As Amended) SOLICITATION TO COMMIT POSSESSION OF MARIJUANA FOR SALE, A CLASS 6 UNDESIGNATED FELONY (KAMO DANIELIAN) in violation of A.R.S. §§ 13-3401, 13-3405, 13-3418, 13-1002, 12-116.04, 12-116.08, 12-269, 13-604, 13-610, 13-701, 13-702, 13-707, 13-801, and 13-802 committed on December 13, 2014.

This is a **non-dangerous, non-repetitive** offense under the criminal code.

Terms: On the following understandings, terms and conditions:

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

1. The crime carries a presumptive sentence of 1 year; a minimum sentence of .5 years; a mitigated sentence of .33 years; a maximum sentence of 1.5 years; and an aggravated sentence of 2 years. Probation is available. Restitution of economic loss to the victim and waiver of extradition for probation revocation procedures are required. Pursuant to A.R.S. §13-805 at the time restitution is ordered the court may enter a criminal restitution order including interest and collection fees. The maximum fine that can be imposed is **$150,000.00 plus an 83% surcharge plus $20.00 pursuant to A.R.S. §12-269 plus a $13.00 assessment pursuant to A.R.S. §12-116.04.** If the Defendant is sentenced to prison, the Defendant shall also be sentenced to serve a term of community supervision equal to one-seventh of the prison term to be served consecutively to the actual period of imprisonment. If the Defendant fails to abide by the conditions of community supervision, the Defendant can be required to serve the remaining term of community supervision in prison. Within 30 days of being sentenced, pursuant to A.R.S. §13-610, the defendant shall provide a sufficient sample of blood or other bodily substance for deoxyribonucleic acid (DNA) testing and extraction to be used for law enforcement identification purposes and/or for use in a criminal prosecution and/or for use in a proceeding under title 36, chapter 37. Special conditions regarding the sentence imposed by statute (if any) are: **Pursuant to A.R.S. §12-116.08, the defendant shall pay a penalty assessment of $15.00. Pursuant to A.R.S. §13-901.01, this offense represents a strike under Prop. 200. Pursuant to A.R.S. §13-3418, on conviction of any offense in Arizona Revised Statute Title 13, Chapter 34, the Court may render the defendant ineligible to receive any public benefits. The Court shall determine the length of time that shall elapse before the defendant's eligibility is restored. Pursuant to A.R.S. §13-604(A), this offense shall be treated as a felony for all purposes until such time as the Court may actually enter an order designating the offense a misdemeanor. If this offense were designated a misdemeanor, the defendant could receive a maximum of 6 months in jail and a maximum fine of $2,500 plus the statutory surcharge.**

2. The parties stipulate to the following additional terms, subject to court approval at the time of sentencing as set forth in paragraph 7: **Defendant shall be placed on supervised probation. The Defendant shall pay for any and all costs associated with the DNA testing required under §13-610. Defendant shall pay a fine of $750.00 plus an 83% surcharge for a total fine of $1372.50. This offense may not be designated a misdemeanor unless and until the defendant successfully completes probation.**

3. The following charges are dismissed, or if not yet filed, shall not be brought against the Defendant by the Maricopa County Attorney's Office: **Counts 2 and 3.**

4. This agreement serves to amend the complaint, indictment, or information, to charge the offense to which the Defendant pleads, without the filing of any additional pleading. However, if the plea is rejected by the court or withdrawn by either party, or if the conviction is subsequently reversed, the original charges and any charges that are dismissed by reason of this plea agreement are automatically reinstated.

5. If the Defendant is charged with a felony, he hereby waives and gives up his rights to a preliminary hearing or other probable cause determination on the charges to which he pleads. The Defendant agrees that this agreement shall not be binding on the State should the Defendant be charged with or commit a crime between the time of this agreement and the time for sentencing in this cause; nor shall this agreement be binding on the State until the State confirms all representations made by the Defendant and his attorney, to-wit: **Defendant avows NO MORE THAN ZERO [0] prior adult felony convictions in any jurisdiction under any names. Defendant avows he WAS NOT on adult felony probation, parole, release, or community supervision at the time of the offense. Defendant avows he has no pending felony matters in any jurisdiction under any names.** If the Defendant fails to appear for sentencing, the court may disregard the stipulated sentence and impose any lawful sentence which is the same as or exceeds the stipulated sentence in the plea agreement. In the event the court rejects the plea, or either the State or the Defendant withdraws the plea, the Defendant hereby waives and gives up his right to a preliminary hearing or other probable cause determination on the original charges.

6. Unless this plea is rejected by the court or withdrawn by either party, the Defendant hereby waives and gives up any and all motions, defenses, objections, or requests which he has made or raised, or could assert hereafter, to the court's entry of judgment against him and imposition of a sentence upon him consistent with this agreement. By entering this agreement, the Defendant further waives and gives up the right to appeal.

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

KD 7. The parties hereto fully and completely understand and agree that by entering into a plea agreement, the defendant consents to judicial fact finding by preponderance of the evidence as to any aspect or enhancement of sentence and that any sentence either stipulated to or recommended herein in paragraph two is not binding on the court. In making the sentencing determination, the court is not bound by the rules of evidence. The State's participation in this plea agreement is conditional upon the Court's acceptance its terms conditions or provisions. If after accepting this plea the court concludes that any of the plea agreement's terms conditions or provisions regarding the sentence or any other aspect of this plea agreement are inappropriate, it can reject the plea. If the court decides to reject any of the plea agreement's terms conditions or provisions, it must give both the state and the Defendant an opportunity to withdraw from the plea agreement. Should the Court reject this plea agreement, or the State withdraws from the agreement, the Defendant hereby waives all claims of double jeopardy and all original charges will automatically be reinstated. The Defendant in such casa waives and gives up his right to a probable cause determination on the original charges.

KD 8. If the court decides to reject the plea agreement provisions regarding sentencing and neither the State nor the Defendant elects to withdraw the plea agreement, then any sentence either stipulated to or recommended herein in paragraph 2 is not binding upon the court, and the court is bound only by the sentencing limits set forth in paragraph 1 and the applicable statutes.

KD 9. This plea agreement in no way affects any forfeiture proceedings pursuant to A.R.S. §13-4301 et seq., §13-2314, or §32-1993, if applicable, nor does the plea agreement in any way compromise or abrogate any civil actions, including actions pursuant to A.R.S. §13-2301 et seq. or §13-4301 et seq., or the provisions of A.R.S. §13-2314 or A.R.S. §13-4310.

KD 10. I understand that if I am not a citizen or if I am a naturalized citizen of the United States that my decision to go to trial or enter into a plea agreement may have immigration consequences. Specifically, I understand that pleading guilty or no contest to a crime may affect my immigration status. Admitting guilt may result in deportation even if the charge is later dismissed. My plea or admission of guilt could result in my deportation or removal, could prevent me from ever being able to get legal status in the United States, or could prevent me from becoming a United States citizen. I understand that I am not required to disclose my legal status in the United States to the court.

KD 11. I have read and understand the provisions of pages one, two, and three of this agreement. I have discussed the case and my constitutional rights with my lawyer. My lawyer has explained the nature of the charge(s) and the elements of the crime(s) to which I am pleading. I understand that by pleading **GUILTY** I will be waiving and giving up my right to a determination of probable cause, to a trial by jury to determine guilt and to determine any fact used to impose a sentence within the range stated above in paragraph one, to confront, cross-examine, compel the attendance of witnesses, to present evidence in my behalf, my right to remain silent, my privilege against self-incrimination, presumption of innocence and right to appeal. I agree to enter my plea as indicated above on the terms and conditions set forth herein. I fully understand that if, as part of this plea agreement, I am granted probation by the court, the terms and conditions thereof are subject to modification at any time during the period of probation. I understand that if I violate any of the written conditions of my probation, my probation may be terminated and I can be sentenced to any term or terms stated above in paragraph one, without limitation.

///

///

///

///

///

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

I have personally and voluntarily placed my initials beside each of the above paragraphs and signed the signature line below to indicate that I read, or had read to me, understood and approved all of the previous paragraphs in this agreement, both individually and as a total binding agreement. My plea is voluntary and not the result of force, or threat, or promises other than those contained in the plea agreement.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT COMPLETELY, OR HAD IT READ TO YOU AND UNDERSTAND IT FULLY.

Date: 2-2-15 Defendant _____
KAMO DANIELIAN

I have discussed this case with my client in detail and advised my client of his or her constitutional rights and all possible defenses. I believe that the defendant's plea is knowing, intelligent, and voluntary and that the plea and disposition are consistent with law.

Date: 2/2/15 Defense Counsel _____ 028847

I have reviewed this matter and concur that the plea and disposition set forth herein are appropriate and are in the interests of justice.

Date: 2/2/15 Prosecutor /s/ _____ 030047
/s/ Benjamin L. Tate

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
02/04/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT

02/02/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
S. Cornfield
Deputy

STATE OF ARIZONA

BENJAMIN L TATE

v.

KAMO DANIELIAN (001)

KRISTI SETZER

APO-PLEAS-CCC

WAIVER OF PRELIMINARY HEARING AND PLEA AGREEMENT ARRAIGNMENT PROCEEDINGS

3:31 p.m.

Courtroom SCT 3B

State's Attorney:	Sara Bruchman
Defendant's Attorney:	Krist Setzer
Defendant:	Present

Defendant was present for the group advisement given on the record at 8:58 a.m. in Courtroom 3B or at 8:50 a.m. in Courtroom 3A this date both in the South Court Tower.

A record of the proceedings is made by audio and/or videotape in lieu of a court reporter.

The Court reviews the Plea Agreement with Defendant. The Court advises Defendant of the range of possible sentence and the availability of probation, and any special conditions of sentencing and probation. The Court advises Defendant of all pertinent constitutional rights and rights of review.

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT 02/02/2015

Defendant enters a plea of Guilty to the following:

OFFENSE: Count 1 (Amended) Solicitation to Commit Possession of Marijuana for Sale
Class 6 Undesignated Felony
A.R.S. § 13-3401, 3405, 3418, 1002, 12-116.04, 116.08, 269, 13-604, 610, 701, 702, 707, 801, and 802
Date of Offense: 12/13/2014
Non Dangerous - Non Repetitive

IT IS ORDERED accepting the plea.

IT IS ORDERED setting time for sentencing on 2/25/2015 at 8:30 a.m. before this division.

IT IS FURTHER ORDERED that the following will be deemed submitted at the time of sentencing: Motion To Dismiss Counts 2 and 3 as reflected in the Plea Agreement.

LET THE RECORD REFLECT the EDC / RCC Adult Probation Office will prepare an expedited presentence report, and that Defendant shall report to the Adult Probation Department if not in custody.

IT IS ORDERED vacating any pending dates.

IT IS FURTHER ORDERED affirming prior release orders.

Filed: Information

3:39 p.m. Matter concludes.

The Superior Court of Arizona in Maricopa County – Adult Probation Department
Chief Probation Officer Barbara A. Broderick

EXPEDITED PRESENTENCE INVESTIGATION

2/25/15 FILED MICHAEL K. JEANES, Clerk 10:40 AM
By A. Noyes, Deputy

State of Arizona v. **Kamo Danielian, CR2014-158850-001-DT**

Superior Court Criminal Division **RCCT3**

Sentencing Date: **February 25, 2015**

Sentencing Judge:	**James Rummage**	Prosecutor:	**Benjamin Tate, DCA**
PSI Officer:	**Karen Vaniman**	Defense Counsel:	**Kristi Setzer, LA**

Present Offense:

The following information is summarized from the Form IV Release Questionnaire Probable Cause Statement related to Phoenix Police Departmental Report #201402176128:

On December 13, 2014, Kamo Danielian utilized a social networking website to offer marijuana for sale. Mr. Danielian agreed to sell twenty-two grams of marijuana to an undercover officer for $200.00. The details of the transaction and a meeting place were negotiated via cellular telephone. Officers contacted Mr. Danielian when he arrived at the meeting place, and there was a strong odor of marijuana detected. Mr. Danielian admitted he was in possession of marijuana. The marijuana was located on the floorboard of Mr. Danielian's vehicle, along with an electronic scale. Another scale was located near the front passenger seat, and Mr. Danielian was in possession of the cellular phone used to negotiate the transaction.

Sentencing Considerations:

Number of Prior Felony Convictions:	0
Prior Drug/Alcohol Treatment:	No
Drug Court/DUI Court Eligible:	No Sales offenses are not eligible for Drug Court.
Identification Status:	ICE has been notified of the defendant's presence in Arizona. A request for legal status was sent on February 4, 2015. ICE records indicate the defendant is a United States Citizen. The defendant has provided documentation verifying his identity in the form of an Arizona Driver License.
Mandatory Financial Assessment:	• Technical Registration Fund in the total amount of $15.00. • Probation Assessment in the total amount of $20.00. • Penalty Assessment A.R.S. 12-116.04 (Investigating Agency: Phoenix PD) in the total amount of $13.00.

The Superior Court of Arizona in Maricopa County – Adult Probation Department
Chief Probation Officer Barbara A. Broderick

State of Arizona v. **Kamo Danielian, CR2014-158850-001-DT**

Probation Available:	Yes
Assessed Risk Level per Offender Screening Tool (OST):	Medium-Low Risk

Additional Considerations:

- The defendant was interviewed by a presentence screener. He stated he got involved with the wrong people. He was working with a friend who had this "app" where he was texting people. His friend told him to download the "app" so they could both use it at the same time. His friend told him there was a guy who wanted something and offered him money for helping him out. The defendant thought it could not hurt, so he went ahead and did it. The guy turned out to be a cop. He does not know if his friend set him up. Regarding sentencing, the defendant will accept whatever the Judge thinks is fair. He does not think the maximum probation is fair due to this being his first offense. He has to take time off of school until probation is done because they do background checks, and if he has a felony, he cannot go to school.
- The defendant is currently employed part-time as a telemarketer with Krasiva. He also works as a caregiver for his grandparents. He reported a monthly income of $800.00 and monthly expenses totaling $1,483.00. He believes he will be able to pay up to $65.00 a month toward Court-ordered fees.
- The defendant reported he drinks alcohol occasionally, but not to the point of intoxication. He denied ever using any illegal drugs.
- The defendant has no prior convictions. Considering the nature of the present offense, a term of supervised probation appears appropriate.

Plea Agreement Considerations:

- None.

Recommendation:

It is respectfully recommended that the offense remain undesignated and that the defendant be granted two year(s) supervised probation to begin on February 25, 2015. Abide by the following additional conditions:

Condition #15 I will be financially responsible by paying all restitution, fines, and fees in my case as imposed by the Court. I understand, if I do not pay restitution in full, the Court may extend my probation.

15b. Probation Service Fee of $65.00 per month.
15d. Drug Fine of $750.00
Plus a surcharge of 83 percent, in the total amount of $1,372.50 in payments of $10.00 per month.
15r. Probation Assessment in the total amount of $20.00.

The Superior Court of Arizona in Maricopa County – Adult Probation Department
Chief Probation Officer Barbara A. Broderick

State of Arizona v. **Kamo Danielian, CR2014-158850-001-DT**

15s. Time Payment Fee of $20.00.
15x. Penalty Assessment A.R.S. 12-116.04 (Investigating Agency: Phoenix PD) in the total amount of $13.00.
15bb. Technical Registration Fund in the total amount of $15.00.

Condition #16 I will not consume or possess any substances containing alcohol.

Reviewed by:

Judge:

Date:

Respectfully submitted by:

Karen Vaniman, Adult Probation Officer
Cell: (602) 619-5440
February 13, 2015
mailto:kvaniman@apd.maricopa.gov
Allison Thompson, Supervisor
Phone: (602) 619-1388

1:30 pm

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA,

Plaintiff,

vs.

KAMO DANIELIAN,

DOB: [redacted]
Booking #: T138302,

Defendant.

CR2014-158850-001

WAIVER OF PRELIMINARY HEARING WITH PLEA AGREEMENT

DECLARATION by defendant as follows.
Defendant is represented by Kristi Setter

I hereby voluntarily waive my right to a preliminary hearing understanding that I will be held to answer and an information will be filed charging me with having committed.

COUNT 1: ATTEMPT TO COMMIT SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 4 FELONY (KAMO DANIELIAN)
COUNT 2: SALE OR TRANSPORTATION OF MARIJUANA, A CLASS 3 FELONY (KAMO DANIELIAN)
COUNT 3: USE OF WIRE COMMUNICATION OR ELECTRONIC COMMUNICATION IN DRUG RELATED TRANSACTIONS, A CLASS 4 FELONY (KAMO DANIELIAN)

All committed on December 13, 2014

This is a non-dangerous, non-repetitive offense under the criminal code.

I understand and acknowledge that:

A. I have a right to a preliminary hearing.
B. I am represented by an attorney now. Further, I know I have a right to an attorney for all further proceedings in this case. If I cannot afford one, then one will be appointed to represent me at this preliminary hearing as well as in the Superior Court for all purposes including trial, free of charge.
C. I am giving up the right to confront and cross-examine witnesses.
D. I am giving up the right to present evidence in my behalf and that I am giving up the right to have the magistrate determine if there is sufficient evidence against me to establish probable cause to hold me to answer in the Superior Court on the above stated charges, as well as the right to a dismissal of charges against me if the evidence is insufficient.

The State of Arizona and the Defendant hereby agree to the following disposition of this case:

Plea: The Defendant agrees to plead GUILTY to:

Count 1: (As Amended) SOLICITATION TO COMMIT POSSESSION OF MARIJUANA FOR SALE, A CLASS 6 UNDESIGNATED FELONY (KAMO DANIELIAN) in violation of A.R.S. §§ 13-3401, 13-3405, 13-3418, 13-1002, 12-116.04, 12-116.08, 12-269, 13-604, 13-610, 13-701, 13-702, 13-707, 13-801, and 13-802 committed on December 13, 2014.

This is a **non-dangerous, non-repetitive offense** under the criminal code.

Terms: On the following understandings, terms and conditions:

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

1. The crime carries a presumptive sentence of 1 year; a minimum sentence of .5 years; a mitigated sentence of .33 years; a maximum sentence of 1.5 years; and an aggravated sentence of 2 years. Probation is available. Restitution of economic loss to the victim and waiver of extradition for probation revocation procedures are required. Pursuant to A.R.S. §13-806 at the time restitution is ordered the court may enter a criminal restitution order including interest and collection fees. The maximum fine that can be imposed is **$150,000.00 plus an 83% surcharge plus $20.00 pursuant to A.R.S. §12-269 plus a $13.00 assessment pursuant to A.R.S. §12-116.04.** If the Defendant is sentenced to prison, the Defendant shall also be sentenced to serve a term of community supervision equal to one-seventh of the prison term to be served consecutively to the actual period of imprisonment. If the Defendant fails to abide by the conditions of community supervision, the Defendant can be required to serve the remaining term of community supervision in prison. Within 30 days of being sentenced, pursuant to A.R.S. §13-610, the defendant shall provide a sufficient sample of blood or other bodily substance for deoxyribonucleic acid (DNA) testing and extraction to be used for law enforcement identification purposes and/or for use in a criminal prosecution and/or for use in a proceeding under title 36, chapter 37. Special conditions regarding the sentence imposed by statute (if any) are: Pursuant to A.R.S. §12-116.08, the defendant shall pay a penalty assessment of $15.00. Pursuant to A.R.S. §13-901.01, this offense represents a strike under Prop. 200. Pursuant to A.R.S. §13-3416, on conviction of any offense in Arizona Revised Statute Title 13, Chapter 34, the Court may render the defendant ineligible to receive any public benefits. The Court shall determine the length of time that shall elapse before the defendant's eligibility is restored. Pursuant to A.R.S. §13-604(A), this offense shall be treated as a felony for all purposes until such time as the Court may actually enter an order designating the offense a misdemeanor. If this offense were designated a misdemeanor, the defendant could receive a maximum of 6 months in jail and a maximum fine of $2,500 plus the statutory surcharge.

2. The parties stipulate to the following additional terms, subject to court approval at the time of sentencing as set forth in paragraph 7: Defendant shall be placed on supervised probation. The Defendant shall pay for any and all costs associated with the DNA testing required under §13-610. Defendant shall pay a fine of $750.00 plus an 83% surcharge for a total fine of $1372.50. This offense may not be designated a misdemeanor unless and until the defendant successfully completes probation.

3. The following charges are dismissed, or if not yet filed, shall not be brought against the Defendant by the Maricopa County Attorney's Office: Counts 2 and 3.

4. This agreement serves to amend the complaint, indictment, or information, to charge the offense to which the Defendant pleads, without the filing of any additional pleading. However, if the plea is rejected by the court or withdrawn by either party, or if the conviction is subsequently reversed, the original charges and any charges that are dismissed by reason of this plea agreement are automatically reinstated.

5. If the Defendant is charged with a felony, he hereby waives and gives up his rights to a preliminary hearing or other probable cause determination on the charges to which he pleads. The Defendant agrees that this agreement shall not be binding on the State should the Defendant be charged with or commit a crime between the time of this agreement and the time for sentencing in this cause; nor shall this agreement be binding on the State until the State confirms all representations made by the Defendant and his attorney, to-wit: Defendant avows NO MORE THAN ZERO [0] prior adult felony convictions in any jurisdiction under any names. Defendant avows he WAS NOT on adult felony probation, parole, release, or community supervision at the time of the offense. Defendant avows he has no pending felony matters in any jurisdiction under any names. If the Defendant fails to appear for sentencing, the court may disregard the stipulated sentence and impose any lawful sentence which is the same as or exceeds the stipulated sentence in the plea agreement. In the event the court rejects the plea, or either the State or the Defendant withdraws the plea, the Defendant hereby waives and gives up his right to a preliminary hearing or other probable cause determination on the original charges.

6. Unless this plea is rejected by the court or withdrawn by either party, the Defendant hereby waives and gives up any and all motions, defenses, objections, or requests which he has made or raised, or could assert hereafter, to the court's entry of judgment against him and imposition of a sentence upon him consistent with this agreement. By entering this agreement, the Defendant further waives and gives up the right to appeal.

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

7. The parties hereto fully and completely understand and agree that by entering into a plea agreement, the defendant consents to judicial fact finding by preponderance of the evidence as to any aspect or enhancement of sentence and that any sentence either stipulated to or recommended herein in paragraph two is not binding on the court. In making the sentencing determination, the court is not bound by the rules of evidence. The State's participation in this plea agreement is conditional upon the Court's acceptance its terms conditions or provisions. If after accepting this plea the court concludes that any of the plee agreement's terms conditions or provisions regarding the sentence or any other aspect of this plea agreement are inappropriate, it can reject the plea. If the court decides to reject any of the plea agreement's terms conditions or provisions, it must give both the state and the Defendant an opportunity to withdraw from the plea agreement. Should the Court reject this plea agreement, or the State withdraws from the agreement, the Defendant hereby waives all claims of double jeopardy and all original charges will automatically be reinstated. The Defendant in such case waives and gives up his right to a probable cause determination on the original charges.

8. If the court decides to reject the plea agreement provisions regarding sentencing and neither the State nor the Defendant elects to withdraw the plea agreement, then any sentence either stipulated to or recommended herein in paragraph 2 is not binding upon the court, and the court is bound only by the sentencing limits set forth in paragraph 1 and the applicable statutes.

9. This plea agreement in no way affects any forfeiture proceedings pursuant to A.R.S. §13-4301 et seq., §13-2314, or §32-1993, if applicable, nor does the plea agreement in any way compromise or abrogate any civil actions, including actions pursuant to A.R.S. §13-2301 et seq. or §13-4301 et seq., or the provisions of A.R.S. §13-2314 or A.R.S. §13-4310.

10. I understand that if I am not a citizen or if I am a naturalized citizen of the United States that my decision to go to trial or enter into a plea agreement may have immigration consequences. Specifically, I understand that pleading guilty or no contest to a crime may affect my immigration status. Admitting guilt may result in deportation even if the charge is later dismissed. My plea or admission of guilt could result in my deportation or removal, could prevent me from ever being able to get legal status in the United States, or could prevent me from becoming a United States citizen. I understand that I am not required to disclose my legal status in the United States to the court.

11. I have read and understand the provisions of pages one, two, and three of this agreement. I have discussed the case and my constitutional rights with my lawyer. My lawyer has explained the nature of the charge(s) and the elements of the crime(s) to which I am pleading. I understand that by pleading GUILTY I will be waiving and giving up my right to a determination of probable cause, to a trial by jury to determine guilt and to determine any fact used to impose a sentence within the range stated above in paragraph one, to confront, cross-examine, compel the attendance of witnesses, to present evidence in my behalf, my right to remain silent, my privilege against self-incrimination, presumption of innocence and right to appeal. I agree to enter my plea as indicated above on the terms and conditions set forth herein. I fully understand that if, as part of this plea agreement, I am granted probation by the court, the terms and conditions thereof are subject to modification at any time during the period of probation. I understand that if I violate any of the written conditions of my probation, my probation may be terminated and I can be sentenced to any term or terms stated above in paragraph one, without limitation.

///

///

///

///

///

State of Arizona vs. KAMO DANIELIAN
CR Number: CR 2014-158850-001
PLEA AGREEMENT

I have personally and voluntarily placed my initials beside each of the above paragraphs and signed the signature line below to indicate that I read, or had read to me, understood and approved all of the previous paragraphs in this agreement, both individually and as a total binding agreement. My plea is voluntary and not the result of force, or threat, or promises other than those contained in the plea agreement.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT COMPLETELY, OR HAD IT READ TO YOU AND UNDERSTAND IT FULLY.

Date: 2-2-15 Defendant _____
KAMO DANIELIAN

I have discussed this case with my client in detail and advised my client of his or her constitutional rights and all possible defenses. I believe that the defendant's plea is knowing, intelligent, and voluntary and that the plea and disposition are consistent with law.

Date: 2/2/15 Defense Counsel _____ 028547

I have reviewed this matter and concur that the plea and disposition set forth herein are appropriate and are in the interests of justice.

Date: 2/2/15 Prosecutor /s/ _____ 030047
/s/ Benjamin L. Tate

To Whom It May Concern:

I have known Kamo Danielian and his family for over 10 years. Ever since I can remember he was always a good child. My family and I were always on good terms with Kamo and his family. Kamo told me that any time I needed anything to just ask and he has always stood by his word. He is a very knowledgeable man and it is always a pleasure talking to him. I have always spent a lot of time with Kamo's grandparents and they too are very nice people. Every time I speak to Kamo's grandfather and grandmother, they always bring up something about Kamo. It seems like Kamo means the world to them. When Kamo's grandmother invites me over for dinner, she has some amazing cooking recipes and is always a good time. They always talk about his schooling and how proud they are of him and everything he accomplished. Kamo is the first of his family to graduate college and pursue further education. Everyone makes mistakes and I hope that this one does not affect Kamo's hopes and dreams along with his grandparents.

1-7-2015

John Hays

[redacted]

[redacted]

1-7-15

Character Letter for Kamo Danielian

To Whom It May Concern

I was initially impressed with Kamo Danielian's enthusiasm, cleverness and professionalism when I first met him 13 years ago in our apartment complex. I was neighbors with Kamo Danielian and his family for a little over 12 years. During this time we met and throughout his life growing up we always had a positive relationship. I have always seen him walking around with his grandfather and playing chess with him as well. I felt that as neighbors, there were not any problems during their time living in the apartments. I would always play video games with Kamo and his younger brother (Leon Danielian) throughout their stay at the apartments.

I also noticed that Kamo was always exceling in his schooling; his ability to do well in school has always been spectacular. I was amazed at how he managed to juggle school, work, and a job all at the same and still succeed. I have heard that he has recently shown success in a rigorous accelerated 3-year pharmacy program as well.

With all these previous life experiences, I feel that Kamo Danielian has always had a positive effect on me and everyone around him.

Sincerely,

Brian

Kamo Danielian's Character Letter:

Ever since Kamo's mother and younger brother moved in next to us, we have always been on good terms. We now this young men for eleven years, and we saw them growing, going to school, etc. Kamo wanted to be tennis pro. The longer Kamo and his mother lived near us, the more and more we have gotten to know them. We knew Kamo's mother and father had a very bad divorce when Kamo and his brother were both very young. Kamo has told me that his father would always talk bad about his mother and vice versa. We were always surprised how Kamo could stay in a neutral standpoint between both of his parents and not favor one over the other. Kamo would always help his mother during her hard times and the same with his father. With each parent talking so bad about the other, it was very strong of Kamo to not choose a side and help both of his parents during their times of need. Both Kamo's mother and father were not raised in this country and had a very hard time to adjusting to the life here. Kamo's mother and father have a very old school mentality about life and would always turn to Kamo for the simplest things. We were very shocked to hear about the recent news with Kamo's father. We hope everything works out for him and his family.

Mario and Mavis Vargas

[redacted] E Rosemonte Dr

Phoenix, Arizona 85050

[redacted]

[redacted]

01/06/2015

X

Mario P. Vargas

Olga Danielian (Kamo Danielian's mother)

[redacted] E Tracy lane

Phoenix, AZ 85032

Court members:

I am writing this for my son Kamo Danielian. My son Kamo has helped me tremendously from work, school, and relocating around Phoenix. He is always a positive person and tries to help out others in any way he can. After his DUI, he has changed and started to drink less even when we all came together as family and attend parties/events. I believe that this DUI has changed the way he behaves and acts around everyone. Kamo has also went back to school, graduated and passed his board exams and now is looking for a job. He is on the right path for success and deserves to have this honor. Please take my words into consideration when making a decision for his set aside.

Thank you,

Olga Danielian

To Whom It May Concern,

I have known Kamo Danielian professionally since January of 2015 when he first joined our team of caregivers. He has been working for us ever since and we have not had any problems with his employment. He is always responsible with getting his requirements for employment done (CPR certifications, sending in time sheets in a timely manner, CEU credit completions, etc..). During the quarterly checkups we have for him, his members are very grateful to have his caregiving services. He has a flexible schedule and is an open minded person. Kamo Danielian has an excellent reputation with people of all ages from the elderly to his peers and is able to connect with them and inspire them to put forth their best efforts. He is organized and never misses any deadlines at work. I recommend to set aside his past so his future would not be so tainted.

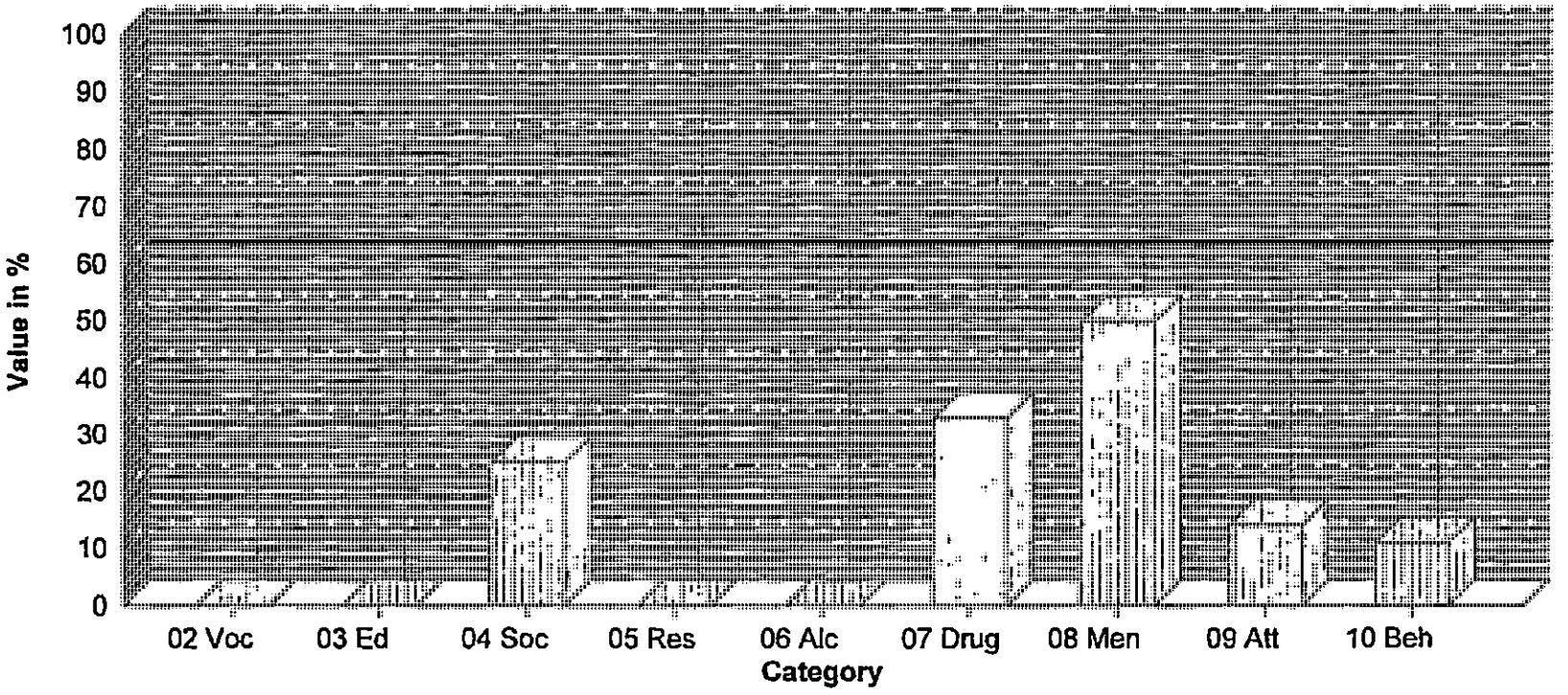
Best,

Oliver Fultz – Instant Care of Arizona Manager
(602) 993-0297
info@instantcareaz.com

Client AZ24103846. Danielian, Kamo DOB [redacted] Age 24

Assessment Date 02/03/2015 As of 02/13/2015

127 Offender Screening Tool (OST) Graph



	02 Voc	03 Ed	04 Soc	05 Res	06 Alc	07 Drug	08 Men	09 Att	10 Beh	
	0%	0%	25%	0%	0%	33%	50%	14%	11%	
Item(s) Not Answered	0	0	0	0	0	1	0	0	0	1

Total OST Score (Sum of all 9 categories) .6 Risk Level Medium-Low Risk

Copyright © ADC, 1999

2/25/15 10:41am
MICHAEL K. JEANES, Clerk
By: [signature]
M. Noyes, Deputy

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
UNIFORM CONDITIONS OF SUPERVISED PROBATION

STATE OF ARIZONA

VS.

Danielian, Kamo

COUNTY/DIVISION: Maricopa / RCCT3

CR: 2014158850-001 DT

§13-901.01 Offense: ☐ 1st ☐ 2nd ☐ Ineligible

PID#: AZ24103846

OFFENSE(S): Count 1 Solicitation to Commit 13-3405A MARIJUANA-POSSESS FOR SALE N 6 U

The Court is suspending imposition or execution of sentence and, under the supervision of the Adult Probation Department (APD),

☑ ***PLACING*** *the defendant on probation for a period of* 9 ☐ *year(s)* ☑ *month(s)* ☐ *day(s)* ☐ *lifetime*
- ☑ *to begin* 2/25/15 *or*
- ☐ *upon absolute discharge from prison for a separate offense or*
- ☐ *upon release from prison for felony DUI (_____ months; _____ days credit)*
- ☐ *upon release from prison pursuant to A.R.S. § 13-603(K)*

☐ ***REINSTATING*** *the defendant on probation for a period of* _____ ☐ *year(s)* ☐ *month(s)* ☐ *day(s)* ☐ *lifetime*
- ☐ *to begin* _____ *with a revised expiration date of* _____

I AGREE TO THE FOLLOWING AS CONDITIONS OF THE SUSPENSION OR THE IMPOSITION OR EXECUTION OF SENTENCE *(Conditions Checked Also Apply)*

LAW ABIDING BEHAVIOR

1. I will maintain a crime-free lifestyle, by obeying all laws, and not engaging or participating in any criminal activity.
2. I will not possess or control any stun guns, tasers, firearms, ammunition, deadly or prohibited weapons as defined in A.R.S. §13-3101.
3. I will report any contact I have with law enforcement to the APD within 72 (or 72) hours.
4. I will submit to search and seizure of person and property by the APD without a search warrant.
5. If deported or processed through voluntary departure, I will not return to the United States without legal authorization during the term of my probation. If I am deported or processed through voluntary departure, all conditions remain in effect except for _____.

REPORTING TO APD

6. I will report to the APD within 72 (or 72) hours of sentencing, absolute discharge from prison, release from incarceration, or residential treatment and continue to report as directed. I will also keep APD advised of progress toward case plan goals and comply with any written directive of the APD to enforce compliance with the conditions of probation. I will provide sample for DNA testing if required by law.

RESIDENCE

7. I will provide the APD safe, unrestricted access to my residence and receive prior approval of the APD before changing my residence. I will reside in a residence approved by the APD.
8. I will request and obtain written permission of the APD prior to leaving the state (☐ county).
9. I may apply for Interstate Compact supervision in the state of _____ and will not proceed to that state until reporting instructions are received and the APD issues a written travel permit.
10. I may apply for an Inter-County transfer and will not proceed to that County until APD issues written authorization.

UNIFORM CONDITIONS OF SUPERVISED PROBATION - PAGE 2 OF 3

STATE OF ARIZONA
VS. Danielian, Kamo

COUNTY/DIVISION: Maricopa / RCCT3
CR / COUNT: 2014158850-001 DT Count: 1

TREATMENT/BEHAVIOR CHANGE/PRO-SOCIAL ACTIVITIES

11. I will actively participate and cooperate in any program of counseling or assistance as determined by APD, or as required by law, given assessment results and/or my behavior. I will sign any release or consent required by the APD so the APD can exchange information in relation to my treatment, behavior and activities.
12. I will not possess or use illegal drugs or controlled substances and will submit to drug and alcohol testing as directed by the APD.
13. I will obtain written approval of the APD prior to associating with anyone I know who has a criminal record. I will not knowingly associate with any person engaged in criminal behaviors.
14. I will seek, obtain, and maintain employment, if legally permitted to do so, and/or attend school. I will inform the APD of any changes within 72 hours.
15. I will be financially responsible by paying all restitution, fines, and fees in my case as imposed by the Court. I understand, if I do not pay restitution in full, the Court may extend my probation.
16. ☑ I will not consume or possess any substances containing alcohol.

SPECIAL REQUIREMENTS

☐ 17. I will complete a total of _____ hours of community restitution. I will complete a set number of hours per month as directed in writing by my probation officer. I will complete these hours at a site approved by the APD.

☐ 18. I will serve _____ ☐ days ☐ month(s), in the county jail beginning _____ with credit for _____ days served, ☐ not to be released until _____. I will report to the APD within 72 (or _____) hours of release from jail. I will comply with all program rules.
☐ Be screened for or ☐ shall participate in Work Furlough, if eligible or ☐ Work Release, if eligible

☐ 19. I will not have any contact with the victim(s) in any form, unless approved in writing by the APD.

☐ 20. I will comply with the following sanctions based on my behavior:
☐ Up to _____ community restitution hours (in addition to any ordered under condition #17), as directed by the APD.
☐ Up to _____ days in the county jail (in addition to any ordered under condition #18), at the discretion of the Court, upon recommendation from the APD.

☐ 21. I will abide by the attached special conditions of probation:
☐ Intensive Probation ☐ Sex Offender ☐ Gang
☐ Domestic Violence ☐ Drug Court ☐ _____
☐ Mental Health ☐ DUI Court/Program

☐ 22. _____

UNIFORM CONDITIONS OF SUPERVISED PROBATION - PAGE 3 OF 3

STATE OF ARIZONA
VS. Danielian, Kamo

COUNTY/DIVISION: Maricopa / RCCT3
CR / COUNT: 2014158850-001 DT Count: 1

Based upon the defendant's agreement to abide by the Conditions of Supervision set forth, above, as well as my review and approval of such conditions, I hereby impose and order that these conditions are in effect, and the defendant shall comply with said conditions.

2/25/15
Judge of the Superior Court Date

RECEIPT AND ACKNOWLEDGMENT: *I acknowledge receipt of the conditions of probation and any attachments added. I understand that by not abiding by the conditions of probation my probation could be revoked and the Court may sentence me in accordance with the law. In addition, I waive extradition for any probation revocation proceedings in this matter.*

2-25-15
Defendant Date

2621 E Beverly Ln		Phoenix	AZ	85032	(602) 410-0479
Defendant's Address	Apt.	City	State	Zip	Phone

DISTRIBUTION: Original - Court, Copies - APD, Defendant

Revision 2010

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
JUDGMENT AND ORDERS OF RESTITUTION, FINES AND FEES

te of Arizona

COUNTY/DIVISION: Maricopa / RCCT3

CASE / CR / COUNT: 2014158850-001 DT Count: 1

Daniellan, Kamo

)#: [redacted]

suant to Uniform Condition 15: I will pay all restitution, fines, and fees in my case as imposed by the Court.*

ancial Sanctions	Total Amount	Payment	Begin Date
a. Total Restitution Ordered**			
b. Monthly Probation Service Fee (PSF) (A.R.S. 13-901)		$25 ~~$65.00~~	4/1/15
c. Delinquent Probation Service Fees			
d. Drug Fine: $750.00 + Surcharge 83% ($622.50) = Total	$1,372.50	$10.00	
e. Non-drug Fine: _____ + Surcharge _____ (_____) = Total			
f. Reimbursement (A.R.S. 11-584 C 3)			
g. DUI Abatement Fund (A.R.S. 28-1382 D 3)			
h. DUI Fine _____ + Surcharge _____ (_____) = Total			
i. DUI Incarceration Cost (A.R.S. 28-1444)			
j. Prison Construction & Operations Fund (A.R.S. 28-1382 D6)			
k. Public Safety Equipment Fund (A.R.S. 28-1382 D7)			
l. Monthly GPS Monitoring Fee (A.R.S. 13-902 G)			
m. Delinquent GPS Monitoring Fees			
n. Sex Offender Registration Violation Assessment (A.R.S. 13-3824 B)			
o. Sex Offender Registration Fee (A.R.S 13-3821 Q)			
p. DUI Fine Warrant Assessment (ARS 28-1525)			
q. Other: _____			
TOTAL PAYMENT MONTHLY =		~~$10.00~~	
per Assessments (paid in conjunction with monthly payment)			
r. Probation Assessment (A.R.S. 12-269)	$20.00		
s. Time Payment Fee (A.R.S. 12-116)	$20.00		
t. Victim Rights Enforcement (A.R.S. 12-116.09)			
u. Warrant Charge (Maricopa County A. O. 2004-199)			
v. Interstate Compact Application Fee***			
w. Inter-county Transfer Fee (A.O. 2009-116)			
x. Penalty Assessment (A.R.S 12-116.04) Agency: Phoenix PD	$13.00		
y. Family Offense Assessment (A.R.S 12-116.06)			
z. Address Confidentiality Program (A.R.S 12-116.05)			
aa. DCAC or Sexual Assault Assessment (A.R.S 12-116.07)			
bb. Technical Registration Fund (A.R.S. 12-116.08)	$15.00		

*Pursuant to A.R.S. 13-805, failure to maintain contact with the Probation Department may result in the issuance of a criminal restitution order in favor of both the State for the unpaid balance, if any, of any fines, costs, fees, or surcharges or assessments imposed; and, in favor of each person entitled to restitution for the unpaid balance of any restitution ordered.

** Probation will automatically be extended pursuant to A.R.S. 13-902 C.

*** Interstate Compact Process and Application Fee: Only one fee per defendant with entire fee due at time of application.

CEIPT AND ACKNOWLEDGMENT: I hereby acknowledge receipt of the Judgment and Orders of Restitution, Fines and Fees and understand my financial obligation to Court and other related parties.

EFENDANT — DATE: 2-25-15 — JUDGE OF THE SUPERIOR COURT — DATE: 2/25/15

00-044 (R12-14)

White: Court File Yellow: APD File Pink: Defendant

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

FILED 2/25/15 10:41 AM
MICHAEL K. JEANES, Clerk
By A. Noyes, Deputy

STATE OF ARIZONA

Plaintiff,

v.

Kamo Danielian

Defendant,

No. CR2014-158850-001

NOTICE OF RIGHTS OF REVIEW AFTER CONVICTION AND PROCEDURE

RIGHT TO APPEAL

You have a right to appeal from a final judgment of conviction, from an order denying a post-trial motion, or from a sentence which is illegal or excessive. Arizona Constitution art. 2, sec. 24; Arizona Revised Statutes Annotated sec. 13-4031 (1978). IF YOU ARE A NONCAPITAL DEFENDANT, YOU DO NOT HAVE A RIGHT TO APPEAL IF YOU HAVE PLEADED GUILTY OR NO CONTEST OR HAVE ADMITTED A VIOLATION OF CONDITIONS OF PROBATION. IN THAT CASE, RELIEF MAY BE SOUGHT ONLY BY PETITION FOR POST-CONVICTION RELIEF. Rules 17.1, 17.2 and 27.8, Rules of Criminal Procedure, Arizona Revised Statutes Annotated sec. 13-4033 (B) (1992).

In order to exercise your right to appeal;

1. You must file a **NOTICE OF APPEAL,** (Form XXIV) **within 20 days of the entry of judgment and sentence. If you do not file a notice of appeal within 20 days you will lose your right to appeal.** The entry of judgment and sentence occurs at the time of sentencing.

2. To file a **NOTICE OF APPEAL,** you should contact your lawyer by letter, telephone or in person, telling him or her that you want to appeal. You can file the notice of appeal before you leave the courtroom on the day you are sentenced if you wish.

3. If you do not have a lawyer, get copies of Forms 5(a) and (b), **Defendant's Financial Statement and Motion for Appointment of Counsel** and Form XXIV (A), **Notice of Appeal,** either from the clerk of the court, jail or prison, fill them out and file or send them to the clerk of the superior court in the county where you were sentenced. They must arrive at the clerk's office within 20 days after you are sentenced.

4. You should have a lawyer handle your appeal.

RIGHT TO POST-CONVICTION RELIEF

You also have a right to petition the superior court for post-conviction relief. Rule 32, Rules of Criminal Procedure, A.R.S. 13-4231.

In order to exercise your right to post-conviction relief,

1. You must file a **NOTICE OF POST-CONVICTION RELIEF** (Form XXIV (b)) **within 90 days of the entry of judgment and sentence** if you do not file, or you do not have the right to file, a Notice of Appeal. If you do appeal, the time you have to file a Notice of Post-Conviction Relief is extended to **within 30 days of the order and mandate affirming the judgment and sentence on direct appeal.** If you do not timely file a Notice of Post-Conviction Relief you may never have another opportunity to have any errors made in your case corrected by another court.

2. To file a **NOTICE OF POST-CONVICTION RELIEF,** you should contact your lawyer by letter, telephone or in person, telling him or her that you want to seek post-conviction relief. You can file the notice of post-conviction relief before you leave the courtroom on the day you are sentenced if you wish.

3. If you do not have a lawyer, get a copy of Form XXIV (b), **NOTICE OF POST-CONVICTION RELIEF,** either from the clerk of the court, jail, or prison, fill it out and file or send it to the clerk of the superior court of the county where you were sentenced. The notice must arrive at the clerk's office within 90 days after you were sentenced or within 30 days of the order and mandate affirming the judgment and sentence on direct appeal.

4. If you cannot afford to hire a lawyer, you should execute the **Affidavit of Indigency** contained in the Notice of Post-Conviction Relief and request that a lawyer be appointed to represent you.

If you want a full copy of the rules governing appeals and post-conviction relief, the clerk of the court in the county where you were convicted will send you one upon request.

RECEIPT BY DEFENDANT

I have received a copy of this notice explaining my right to appeal, my right to seek post-conviction relief and the procedures I must follow to exercise these rights.

DATE 2/25/15

DEFENDANT [signature]

Form XXIII
3899-050 R12-10

Michael K. Jeanes, Clerk of Court
*** Filed ***

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-[illegible] 02/23/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
A. Noyes
Deputy

STATE OF ARIZONA BENJAMIN [illegible]

[illegible] (001)
DOB: [redacted]

KRISTI SELZER

APP-SENTENCINGS-CCC
APPEALS-CCC
DISPOSITION CLERK-CSC
RFR

SUSPENSION OF SENTENCE - PROBATION GRANTED

10:30 a.m.

Courtroom SCT-3D

State's Attorney: Catherine Ferguson-Gilbert
Defendant's Attorney: Kristi Selzer
Defendant: Present

A record of the proceedings is made by audio and/or videotape in lieu of a court reporter.

Count(s) 1: WAIVER OF TRIAL - The Defendant knowingly, intelligently and voluntarily waived all pertinent constitutional and applicable rights and entered a plea of guilty.

IT IS THE JUDGMENT of the Court Defendant is guilty of the following:

OFFENSE: Count 1, as amended: Solicitation to Commit Possession of Marijuana for Sale

Docket Code 109 Form R109B-10 Page

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR 2015-158350-001 DT 02/25/2015

Case is under advisement.

Charges: 1) 13-1405 - A 2) 13-1406 - A 3) 13-1416 - A 4) 28-1383 (A)(2) 5) 13-3405 (A)(1) 6) 13-3407 (A)(1) 7) 13-3407 (A)(3)

Date of Offense: December 3, 2014

Dangerous - Non-Surveillance

The Court considers the expertise or experience of persons and, under the supervision of Arizona Department (AZD), places the Defendant on probation for:

Count 1 Probation Term: 0 months

To begin 02/25/2015

Conditions: Reside in the AZD within 72 hours of sentencing, absolute discharge from the AZD, release from confinement, or as directed and continue to report as directed. Keep AZD informed of any change of address and comply with any written directive of the AZD to enforce compliance with the conditions of probation. Provide DNA testing if required by law.

Commit to the Director of the AZD until further permission of the AZD grant to leaving the state.

Comply with Restitution Terms and Fees.

SUPERVISION SERVICE FEE: Count 1: $25.00 per month, beginning 04/01/2015.

FINE: Count 1: Total amount of $1172.50, which includes surcharge of 83% payable $1.00 a month beginning 04/01/2015.

Fine is to be paid to the Criminal Drug Enforcement Fund.

RESTITUTION/ASSESSMENT: Account - $220.00 payable on 04/01/2015.

Count 1: [illegible] pursuant to A.R.S. § 12-116 in the amount of $20.00 payable on 04/01/2015.

PENALTY ASSESSMENT: A.R.S. § 12-116.04 - Count 1 - $13.00 payable on 04/01/2015.

Investigation Agency: [illegible] Police Department

Minute Entry 02/25/2015 Page 2

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2013-150157-001 DT 02/25/2015

Order to Submit to Court-Ordered Reasonable Blood Sample [CR2015]

Minute entry filed through the Clerk of the Superior Court

IT IS FURTHER ORDERED that Defendant shall submit to fingerprint identification process in the Maricopa County Sheriff's Office if directed to do so by the Adult Probation Department. The Adult Probation Department shall arrange for Defendant to be placed in procedure after one already scheduled. Defendant shall bring identification (SID) number to submit to fingerprint processing.

Pursuant to the provisions of A.R.S. § 13-905 that failure to maintain contact with the Probation Department may result in the following:

A criminal fee [illegible] per month or any part of a month the unpaid balance of any court-ordered fine, restitution, fees, surcharges or assessments imposed.

A criminal restitution order in favor of each person entitled to restitution for the unpaid balance of any restitution ordered.

IT IS ORDERED [illegible] Domestic Violence Counseling [illegible] Counts 2 and 3.

IT IS FURTHER ORDERED that Defendant shall submit to DNA testing for law enforcement identification purposes in accordance with A.R.S. 13-610.

[illegible] Presentence.

Docket Code 019 Form R Page 2

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

COMMISSIONER JAMES RUMMAGE

DIV. [illegible]

DEPUTY CLERK OF THE COURT

No. CR [illegible]

STATE V. [illegible]

[illegible] and hereby [illegible] Defendant's [illegible] is permanently affixed to the [illegible] sheet in open court.

[illegible]

JUDICIAL OFFICER OF THE SUPERIOR COURT

Commissioner James Rummage

Date: Mar 6, 2015

AZ DEPARTMENT OF PUBLIC SAFETY
PCN ACTIVITY REPORT

NOTE: ADDITIONS OR DELETIONS MAY BE MADE AT ANY TIME. A NEW COPY SHOULD BE REQUESTED WHEN NEEDED FOR SUBSEQUENT USE.
DATA TO BE USED ONLY FOR CRIMINAL JUSTICE OR OTHER LAWFUL PURPOSES

PCN	CNT	ARR ARS CODE	ARR STATUTE DESC	ARR OFF TYP	DATE OF OFFENSE	DISPO ORI	DISPO DATE	DISPO ARS CODE	DISPO STATUTE DESC	DIS OFF TYP	DISPO CASE NO	DIS
PCN: 2634109156 SID Number: AZ24103846												
Name: DANIELIAN, KAMO DOB: [redacted] DOA: 2014/12/13 AAO: AZ0072300 AAN: PHX201412130800												
2634109156	1	13-3405A4	MARIJ-TRANSPORT AND/OR SELL	F	12/13/2014	AZ007035J	02/25/2015	13-3405	MARIJUANA VIOLATION	F	CR2014-158850-001	GG
	2	13-3405A4	MARIJ-TRANSPORT AND/OR SELL	F	12/13/2014	AZ007035J	02/25/2015	13-3405A4	MARIJ-TRANSPORT AND/OR SELL	F	CR2014-158850-001	CD
	3	13-3415A	DRUG PARAPHERNALIA-POSSESS/USE	F	12/13/2014							
	4	13-3415A	DRUG PARAPHERNALIA-POSSESS/USE	F	12/13/2014							
	5	13-3417A	USE ELEC COMMUN DRUG TRANSACT	F	12/13/2014	AZ007035J	02/25/2015	13-3417A	USE ELEC COMMUN DRUG TRANSACT	F	CR2014-158850-001	CD

MICHAEL A JEANES, CLERK
BY [signature] DEP
FILED
15 MAR 10 PM 12:32

AZ007035J

K. Kline

URGENT

Person Filing: Kamo Danielian
Address (if not protected): [redacted] E Beverly Lane
City, State, Zip Code: Phoenix, AZ 85032
Telephone: [redacted]
Email Address: [redacted]
Lawyer's Bar Number:

MICHAEL K. JEANES, CLERK
BY DEP
FILED
15 MAR 19 PM 12:43
FOR CLERK'S USE ONLY

Representing ☑ Self, without a Lawyer or ☐ Attorney for ☐ Petitioner OR ☐ Respondent

SUPERIOR COURT OF ARIZONA
IN MARICOPA COUNTY

CR-2014

State of Arizona
Plaintiff

CR Number: 158850-001

Title: MOTION to lessen probation time period or Change to unsupervised probat

Vs.

Kamo Danielian
Name of Defendant

(The section below must be written to explain your request - what you want the judge to order if he/she grants your request (or Motion). If the judge agrees with your request, he/she will sign the attached Order or issue a "minute entry" noting his/her decision.)

I Kamo Danielian am currently on Supervised probation for 9 months. I am also enrolled in MCPHS (Massachusetts college of Pharmacy & Health Sciences). I took a year off of School due to a family matter & am scheduled to return in May 2015 (May 16th). Due to the terms of my Probation I cannot leave the State and therefore cannot attend School. After speaking to my Probation officer (Elizabeth Fenton) She informed me that I cannot leave the State, which was contrary to what my public defender told during the preliminary Sentencing court proceed. My Schooling is very important to both my family and I. I am currently in debt ~100 K and am Scheduled to start making payment towards my loans Soon. I am asking this motion to be processed So I can return to school in May 2015. At the time of Sentencing Please lessen probation term to 4 months of Change probation term from supervised to unsupervised So I can leave the State to finish school.

Judge of Superior Court my right to go back to School

Today's Date: 3-19-15 Your Signature: [signature]

© SUPERIOR COURT OF ARIZONA IN MARICOPA COUNTY
ALL RIGHTS RESERVED
5870

GNCR10f-071312.

This page must be completed and attached to the last page of your motion/request.

I have filed the ORIGINAL of the attached document(s) on 3 (Month) 19 (Day), 2015, with the Clerk of the Superior Court of Arizona in Maricopa County.

I have mailed/delivered a COPY of the attached document(s) on 3 (Month) 19 (Day), 2015, to Judge _____. *(The Judge assigned to your case)*

I have mailed/delivered a COPY of the attached document(s) on 3 (Month) 19 (Day), 2015, to COUNTY ATTORNEY 301 W Jefferson (Address).

By signing below, I promise that I have filed/mailed the attached document(s) as shown above. I understand that if I do not file/mail the attached document(s) as shown above, the judge in my case will not read my request/motion.

Your signature

© SUPERIOR COURT OF ARIZONA IN MARICOPA COUNTY
ALL RIGHTS RESERVED

5870

GNCR10f-071312

WILLIAM G MONTGOMERY
MARICOPA COUNTY ATTORNEY

John E. Brinker
Deputy County Attorney
Bar ID #: 019005
175 W. Madison St.
Phoenix, AZ 85003
Telephone: (602) 372-0290
MCAO Firm #: 00032000
Attorney for Plaintiff

MICHAEL K JEANES, CLERK
BY J Harbaugh DEP
FILED
15 MAR 24 PM 4:41

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA,

Plaintiff,

vs.

KAMO DANIELIAN,

Defendant.

CR2014-158850-001

RESPONSE TO MOTION TO MODIFY PROBATION

(Assigned to the Honorable James R Rummage, Div. RCCT3)

The State of Arizona, by and through undersigned counsel, hereby responds to Defendant's Motion to Modify and resists Defendant's request. Defendant entered into a plea agreement wherein he stipulated to being placed on supervised probation. Defendant, at this point, has been on probation for approximately one month. Defendant's probation grant by the Court was for 9 months. The State respectfully submits that considering the nature of the offense (a marijuana sale incident) that both the supervision and length of probation should remain unchanged given how short a time period Defendant has presently been on probation.

Submitted March 24, 2015.

WILLIAM G MONTGOMERY
MARICOPA COUNTY ATTORNEY

BY: _____
John E Brinker
Deputy County Attorney

Copy mailed\delivered
March 24, 2015,
to:

The Honorable James R Rummage, Div. RCCT3
Judge of the Superior Court

Kamo Danielian
Pro Se
2621 E. Beverly Lane
Phoenix Arizona 85032

BY: _____
John E Brinker
Deputy County Attorney

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
04/22/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT 04/17/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
S. Cornfield
Deputy

STATE OF ARIZONA BENJAMIN L TATE

v.

KAMO DANIELIAN (001) KRISTI SETZER

CONTINUANCE

2:58 p.m.

Courtroom SCT 3B

State's Attorney:	Veronica Dahmer
Defendant's Attorney:	Kristi Setzer
Defendant:	Present

A record of the proceedings is made by audio and/or videotape in lieu of a court reporter.

This is the time set for Status Conference regarding the Defendant's Pro Per Motion to Lessen Probation Time Period or Change to Unsupervised Probation.

For reason(s) as stated on the record,

IT IS ORDERED continuing the Status Conference in the above-entitled cause number to 4/23/2015 at 8:30 a.m. in the Downtown Regional Court Center.

3:16 p.m. Matter concludes.

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
04/29/2015 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CR2014-158850-001 DT

04/23/2015

COMMISSIONER JAMES RUMMAGE

CLERK OF THE COURT
L. Diggs
Deputy

STATE OF ARIZONA

v.

KAMO DANIELIAN (001)

BENJAMIN L TATE

KRISTI SETZER

APO-CCC

MINUTE ENTRY

10:53 a.m.

Courtroom 3B - South Court Tower

State's Attorney:	Josh Maxwell for Benjamin Tate
Defendant's Attorney:	Kristi Setzer
Defendant:	Present

A record of the proceedings is made by audio and/or videotape in lieu of a court reporter.

This is the time set for Status Conference Re: Defendant's Motion to Lessen Probation.

Court, counsel and Defendant discuss the terms of Defendant's probation.

LET THE RECORD REFLECT the Court has been advised that the Adult Probation Department intends to submit an Early Termination Request for the Defendant.

10:57 a.m. Matter concludes.

SUPERIOR COURT OF THE STATE OF ARIZONA
MARICOPA COUNTY

FILED 5/15/2015 8:00 am
MICHAEL K. JEANES, Clerk
By M McKinney
N. McKinney, Deputy

Division CRC15
Pros Atty: DCA
APO Elizabeth Ann Forton, NE

THE STATE OF ARIZONA
VS.
KAMO DANIELIAN
DOB: [redacted]

Case Number: **CR2014-158850-001-DT**

PETITION FOR EARLY TERMINATION OF PROBATION OR UNSUPERVISED PROBATION

The defendant was formally judged guilty of the crime of **COUNT 1: SOLICITATION TO COMMIT POSSESSION OF MARIJUANA FOR SALE, A CLASS 6 UNDESIGNATED FELONY.**

Probation Start Date: 02/25/2015 Prob. Length: 9 month(s) Standard

It is respectfully recommended that the defendant's probation be terminated for the following reasons:
The defendant has credit for 44 earned time credit days as of April 30, 2015. That would put his discharge charge date from probation at October 12, 2015.

The defendant's performance on probation thus far makes him eligible for an early termination of probation. He paid court monies in full, submitted to six negative drug tests, maintained stable employment and residence and reported as directed. The defendant attends pharmacy school in Massachusetts and he would like to terminate from probation to be able to return there and attend school. It is respectfully recommended that probation in this cause be early terminated.

It is recommended the offense be designated a misdemeanor.

Victim Status: There is no victim involved in this case.

Dated this 29 day of April, 2015 E. A. Forton
EAF:em/04/28/2015
Probation Officer Elizabeth Ann Forton Phone 602-619-1842

☑ **IT IS ORDERED that the foregoing petition for early termination will be granted by this court 30 days from this date unless written objection thereto is filed not less than 72 hours before said date. A copy of this petition is herewith transmitted to the prosecuting attorney.**

☐ **IT IS ORDERED denying the petition for early termination. It is further ordered that the defendant be placed on unsupervised probation, deleting all conditions except Condition #1 and continue to pay Probation Service Fees as previously ordered by the Court. If the defendant obeys all laws it is ordered that unsupervised probation be automatically terminated on _____. This expiration date reflects granted Earned Time Credit.**

☐ **IT IS ORDERED** _____

Dated this 6th day of May, 2015.

Judge of the Superior Court
Commissioner James Rummage

PETITION FOR EARLY TERMINATION OF PROBATION OR UNSUPERVISED PROBATION

cc: APD File Court (Original) Pros Atty.

APD Macros Rev. 07/19/2011

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
R. Krane, Deputy
6/2/2015 6:38:22 PM
Filing ID 6641230

WILLIAM G. MONTGOMERY
MARICOPA COUNTY ATTORNEY

Sarah Corcoran
Deputy County Attorney
Bar ID #: 020131
MCAO Firm #: 00032000
Administration Building
301 W Jefferson St, Ste 800
Phoenix, AZ 85003-2143
Telephone: (602)506-8527
mcaoctd@mcao.maricopa.gov
Attorney for Plaintiff

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

THE STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	CR2014-158850-001 STATE'S RESPONSE TO ADULT PROBATION OFFICE'S PETITION FOR EARLY TERMINATION OF PROBATION OR MODIFICATION TO UNSUPERVISED PROBATION AND RECOMMENDATION FOR MISDEMEANOR DESIGNATION (Assigned to the Honorable James Rummage)

Pursuant to Arizona Rule of Criminal Procedure 27.3, the State of Arizona, by and through undersigned counsel, hereby responds to the Adult Probation Office's Petition for Early Termination of Probation and recommendation for misdemeanor designation. The State objects to both for the following reasons:

The defendant was charged with, among other things, 2 counts of Sale or Transportation of Marijuana, both Class 3 Felonies. He pled to Solicitation to Commit Possession of Marijuana for Sale, a Class 6 Undesignated Felony. The defendant was afforded a supervised probation grant of 9 months on 02/25/2015.

This offense involved sale of marijuana. Illegal drugs contribute to the degradation of our community. Given the serious nature of the drug trade, continued supervision is imperative to protect against re-offending.

The defendant has greater than six months left in his original probation grant. The defendant is on probation to ensure rehabilitation and community safety. Terminating probation at this time increases the likelihood of recidivism and jeopardizes the community.

In addition, the defendant was given the benefit of having the offense remain undesignated and should serve the remainder of the term to earn the designation of the offense as a misdemeanor.

For the reasons stated above, the State objects to early termination of this defendant's probation at this time and respectfully requests this Court affirm the defendant's current

//

//

//

probation grant.

Respectfully submitted this 2nd day of June, 2015.

WILLIAM G. MONTGOMERY
MARICOPA COUNTY ATTORNEY'S OFFICE

BY /s/_____
/s/Sarah Corcoran
Deputy County Attorney

Copy of the foregoing mailed/
e-filed / delivered this
2nd day of June 2015, to:

The Honorable James Rummage
Commissioner of the Superior Court

Elizabeth Ann Forton, NE
Adult Probation Department
620 West Jackson, 3rd Floor
Phoenix, Arizona 85003

BY /s/_____
/s/Sarah Corcoran
Deputy County Attorney

SC:vfb

610

SUPERIOR COURT OF THE STATE OF ARIZONA
MARICOPA COUNTY

FILED 10/8/15 2:00pm
MICHAEL K. JEANES, Clerk
By A Callahan
A. Callahan, Deputy

Division CRC15
Pros Atty DCA
APO Elizabeth Ann Forton, NE

THE STATE OF ARIZONA
VS.
KAMO DANIELIAN
DOB: [redacted]

Case Number: **CR2014-158850-001-DT**

ORDER OF DISCHARGE FROM PROBATION

The defendant was formally judged guilty of the crime of **COUNT 1: SOLICITATION TO COMMIT POSSESSION OF MARIJUANA FOR SALE, A CLASS 6 UNDESIGNATED FELONY.**

Probation Start Date: 02/25/2015 Prob. Length: 9 month(s) Standard

Please see attached Petition for Early Termination of Probation.

Dated this 29 day of April, 2015 E A Forton
EAF:em/04/28/2015
Probation Officer Elizabeth Ann Forton Phone 602-992-8507

IT IS ORDERED pursuant to Rule 27.4(A) that the defendant is hereby discharged from probation in this case effective 6/25/15.

☐ **THE COURT NOTES the defendant failed to comply with conditions** _____

☒ **IT IS ORDERED the undesignated offense:** ☐ **REMAIN UNDESIGNATED*;** ☒ **Be Designated a MISDEMEANOR**
*Notice: The defendant may request misdemeanor designation for an undesignated offense; see A.R.S. 13-604. All requests must be submitted to the Court in writing and provide detailed reasons to support the request.

Dated this 5th day of June, 2015.

Judge of the Superior Court
Commissioner James Rummage

ORDER OF DISCHARGE FROM PROBATION

cc: Court (Original) APD File Defendant Pros Atty.

APD Macros

Rev. 07/19/2011

FILED

DATE: 06/10/2015

TIME: 3 : 34 ☐AM ☒PM

MICHAEL K. JEANES

BY: R. SMYTH DEPUTY

COURT DISPOSITION REPORT SUPPLEMENTAL

SUPERIOR COURT CASE NUMBER: CR 2014-158850-001

DATE OF ORIGINAL DISPOSITION: 02/25/2015

AKAS:

1. SID NUMBER	2. LAST NAME: DANIELIAN SUFFIX: FIRST: KAMO MIDDLE:	3. DOB	4. PCN NUMBER
[redacted]		[redacted]	2634109156
5. ARRESTING AGENCY ORI NUMBER: AZ0072300	6. ARREST NUMBER: PHX201412130800	7. DATE OF ARREST: 12/13/14	
DISPOSITIONS ARE TO ALL COUNTS UNLESS OTHERWISE NOTED	SUBMITTED By: AZ 007035J Maricopa County Clerk of Superior Court 601 West Jackson, Phoenix, AZ 85003		

DISPOSITION DATE	DISPOSITION
06/05/15	PROBATION DISCHARGE/ CT 1 NOW DESIGNATED A MISDEMEANOR.

DRS

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
S. Kennow, Deputy
12/15/2015 3:34:52 PM
Filing ID 7068166

Scott A. Maasen
Arizona State Bar No. 018073
MAASEN LAW FIRM
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
office@maasenlaw.com
480-778-1500 (Tel)
480-778-0514 (Fax)
Attorneys for Defendant

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	Case No. CR2014-158850-001 DT **APPLICATION TO SET ASIDE JUDGMENT / RESTORE CIVIL RIGHTS / RESTORE RIGHT TO POSSESS FIREARM PURSUANT TO A.R.S. §§ 13-907, 13-912 AND 13-905**

Defendant Kamo Danielian, by and through undersigned counsel, hereby requests this Court to set aside his judgment of guilt, restore her civil rights and restore his right to possess or carry a gun or firearm pursuant to A.R.S. §§ 13-907, 13-912 and 13-905. This Motion is supported by the attached Memorandum of Points and Authorities.

RESPECTFULLY SUBMITTED this ___ day of December, 2015.

MAASEN LAW FIRM

_____
Scott A. Maasen
Attorneys for Defendant

///
///

MEMORANDUM OF POINTS AND AUTHORITIES

I. Factual and Procedural History

On February 25, 2015, Mr. Danielian pled guilty to Solicitation to Commit Possession of Marijuana for Sale a Class 6 Felony, pursuant to a plea agreement. On the same date, Mr. Danielian was sentenced to one (9) months of supervised probation. On May 8, 2015, Mr. Danielian was successfully discharged from probation.

Since being discharged from probation, Mr. Danielian has maintained employment and a stable residence. Mr. Danielian has significant community support. Furthermore, it appears that Mr. Danielian has remained law-abiding since his conviction in this matter. It appears that the event which led to the conviction in this matter was an isolated situation as Mr. Danielian has exhibited no similar behavior since being discharged from probation.

Ms. Danielian now wants to finally close this uncharacteristic chapter of his life by requesting that this honorable court set aside the judgment of guilt in this matter. Mr. Danielian has been a law-abiding, hard-working, and successful man since the offense date in this matter. He has fully completed all of his obligations in the underlying matter and wishes to ensure that his civil rights are restored.

II. Legal Standard

Every person convicted of a criminal offense may, upon fulfillment of the conditions of probation or sentence and discharge by the court, apply to the judge who pronounced sentence or such judge's successor in office to have the judgment of guilt set aside. See, A.R.S. § 13-907(A). If the judge grants the application, the judge shall set aside the judgment of guilt, dismiss the accusations or information and order that the person be released from all penalties and disabilities resulting from the conviction. See, Id.

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 | F: (480) 778-0514

Upon completion of the term of probation, or upon absolute discharge from imprisonment, and upon the completion of payment of any fine or restitution imposed, any person who has not previously been convicted of any other felony shall automatically be restored any civil rights which were lost or suspended by the conviction. A.R.S. § 13-912(A). Further, a person who has been discharged from probation may have any civil rights which were lost or suspended by the felony conviction restored. See A.R.S. § 13-905 (B).

III. Argument

Defendant realizes he made a serious mistake when he committed the current offense. He accepted responsibility and pled guilty. As far as counsel is aware, this case represents the only adult criminal convictions Mr. Danielian has suffered during his lifetime. He has complied with and completed all the terms of his probation.

As described above, Mr. Danielian has remained law-abiding since committing the current offenses. Additionally, Mr. Danielian has the support of family and friends and presents virtually no risk to re-offend. Mr. Danielian has demonstrated he is a stable, contributing member of society. Removal of this conviction from Mr. Danielian record will enable him to put this in his past and move on with his life. Based on his exceptional performance thus far, Counsel respectfully requests that the Court set aside the judgment of guilty pursuant to A.R.S. § 13-907.

IV. Conclusion

For the foregoing reasons, Defendant Kamo Danielian respectfully requests that this Court set aside his judgments of conviction pursuant to A.R.S. § 13-907, to restore his civil rights pursuant to A.R.S. § 13-912, and restore his right to possess or carry a gun or firearm pursuant to A.R.S § 13-905.

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

///

RESPECTFULLY SUBMITTED this 15th day of December, 2015.

MAASEN LAW FIRM

/s/ Scott A. Maasen
Scott A. Maasen
Attorneys for Defendant

Original of the foregoing via e-filing system
this 15th day of October, 2010, to:

Clerk of the Court
MARICOPA COUNTY SUPERIOR COURT
201 W. Jefferson St.
Phoenix, Arizona 85003

Copies of the foregoing via e-filing system
this 15th day of October, 2010, to:

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: /s/ Toni Gaytan

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1300 / F: (480) 778-0514

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	Case No. CR2014-158850-001 DT **ORDER SETTING ASIDE JUDGMENT, RESTORING DEFENDANT'S CIVIL RIGHTS AND RESTORING DEFENDANT'S RIGHT TO POSSESS FIREARMS PURSUANT TO A.R.S §§ 13-907, 13-912 AND 13-905**

A Motion to Set Aside Judgment/Restore Civil Rights/Restore Right to Possess Firearms having been filed by the Defendant, with good cause appearing;

IT IS HEREBY ORDERED that Defendant Kamo Danielian shall receive a full restoration of his civil rights, including his right to possess a firearm, pursuant to A.R.S. §§ 13-905 and 13-912.

IT IS FURTHER ORDERED setting aside Defendant's judgment of conviction pursuant to A.R.S. § 13-907. Defendant's judgment of guilt as well as any felony information, indictment or other accusation underlying the judgment of guilt are hereby dismissed and Defendant is released from all penalties and disabilities resulting from her conviction in the above captioned cause.

DATED this ____ day of _____, 2010.

_____

JUDGE OF THE SUPERIOR COURT

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255

COPIES of the foregoing mailed this
_____ day of _____, 2015 to:

Scott A.Maasen
MAASEN LAW FIRM
8707 E. Vista Bonita Dr., Ste. 230
Scottsdale, AZ 85255
Attorneys for Defendant

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: _____

MICHAEL K. JEANES, CLERK
BY [signature] DEP
FILED
15 DEC 17 AM 11:58

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

STATE OF ARIZONA
Plaintiff,
VS.
KAMO DANIELIAN
Defendant,

Case Number:
CR2014-158850-001

NOTICE

The Court has received Defendant's Application for:

Applied For:

No	Motion for Reconsideration
Yes	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	Vacating the judgment of guilt and dismissing the charges against the Defendant as stated in the application herein.

This Application will be considered on or after the date of Monday, January 18, 2016
This is not a hearing. The application is ruled upon in a closed session and no appearance is required. The parties will be notified by mail upon ruling.

DATED this day, Tuesday, December 15, 2015

Master Calendar Commissioner, Judge Pro Tem of the Superior Court

Maricopa County

Clerk of the Superior Court

Michael K Jeanes, Clerk of Court
*** Electronically Filed ***
K. Curtner, Deputy
12/21/2015 4:28:09 PM
Filing ID 7079715

Criminal Financial Obligations
Restoration of Civil Rights Information Sheet

Date: Wednesday, December 16, 2015
Case Name: KAMO DANIELIAN
Case Number: CR2014-158850-001

The individual listed above has the following debts:

Restitution Amount:	$ 0.00
Probation Fees Amount:	$ 50.00
Fine Base Amount:	$ 0.00
Fine Surcharge:	$ 0.00
Reimbursement Amount:	$ 0.00
Time Payment Amount:	$ 0.00
Probation Assessment:	$ 0.00

OTHER Fees:

_____	$ 0.00
_____	$ 0.00
_____	$ 0.00
_____	$ 0.00
Grand Total:	$ 50.00

Notes: _____
BALANCE DUE.

F-CFO-1006 Rev.: L.R.D.: 08/14/2015

MICHAEL K JEANES, CLERK
BY J Harbaugh DEP
FILED
16 JAN 25 PM 1:22

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

STATE OF ARIZONA	**Plaintiff**	**Case Number:**
vs.		**CR 2014-158850-001**
KAMO DANIELIAN	**Defendant**	
		ORDER

The Court has received the Defendant's Application, given proper notice and considered any response filed by the State.

IT IS ORDERED:

Applied For:	Granted	Denied	
☒	☐	☒	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
☒	☐	☒	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
☒	☐	☒	Setting Aside the judgment of guilt, dismissing the accusations or information and releasing the Defendant from all applicable penalties and disabilities resulting from the conviction.

Reason for denial: This court will not consider your application until fees of **$50.00** have been paid. You may resubmit your application once all fees have been paid.

Dated: Jan 11, 2016

R L Gottfried

Judge of the Superior Court

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
S. Kennow, Deputy
3/8/2016 3:18:49 PM
Filing ID 7251505

Scott A. Maasen
Arizona State Bar No. 018073
MAASEN LAW FIRM
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
office@maasenlaw.com
480-778-1500 (Tel)
480-778-0514 (Fax)
Attorneys for Defendant

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	Case No. CR2014-158850-001 DT **APPLICATION TO SET ASIDE JUDGMENT / RESTORE CIVIL RIGHTS / RESTORE RIGHT TO POSSESS FIREARM PURSUANT TO A.R.S. §§ 13-907, 13-912 AND 13-905**

Defendant Kamo Danielian, by and through undersigned counsel, hereby requests this Court to set aside his judgment of guilt, restore his civil rights and restore his right to possess or carry a gun or firearm pursuant to A.R.S. §§ 13-907, 13-912 and 13-905. This Motion is supported by the attached Memorandum of Points and Authorities.

RESPECTFULLY SUBMITTED this ___ day of March, 2016.

MAASEN LAW FIRM

_____
Scott A. Maasen
Attorneys for Defendant

///
///

MEMORANDUM OF POINTS AND AUTHORITIES

I. Factual and Procedural History

On February 25, 2015, Mr. Danielian pled guilty to Solicitation to Commit Possession of Marijuana for Sale a Class 6 Felony, pursuant to a plea agreement. On the same date, Mr. Danielian was sentenced to nine (9) months of supervised probation. On May 8, 2015, Mr. Danielian was successfully discharged from probation. Mr. Danielian filed a previous motion to set aside the conviction and restore his civil rights and right to possess a firearm on December 15, 2015 but was denied due to Mr. Danielian having a past-due balance on probation fees. Mr. Danielian has completed payment of all of his fees as of this date.

Since being discharged from probation, Mr. Danielian has maintained employment and a stable residence. Mr. Danielian has significant community support. Furthermore, it appears that Mr. Danielian has remained law-abiding since his conviction in this matter. It appears that the event which led to the conviction in this matter was an isolated situation as Mr. Danielian has exhibited no similar behavior since being discharged from probation.

Ms. Danielian now wants to finally close this uncharacteristic chapter of his life by requesting that this honorable court set aside the judgment of guilt in this matter. Mr. Danielian is set to graduate in May, 2016 and wants to ensure he is able to find gainful employment upon completion of his degree. Mr. Danielian has been a law-abiding, hard-working, and successful man since the offense date in this matter. He has fully completed all of his obligations in the underlying matter and wishes to ensure that his civil rights are restored.

II. Legal Standard

Every person convicted of a criminal offense may, upon fulfillment of the conditions of probation or sentence and discharge by the court, apply to the judge who pronounced sentence or

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

such judge's successor in office to have the judgment of guilt set aside. A.R.S. § 13-907(A). If the judge grants the application, the judge shall set aside the judgment of guilt, dismiss the accusations or information and order that the person be released from all penalties and disabilities resulting from the conviction. Id.

Upon completion of the term of probation, or upon absolute discharge from imprisonment, and upon the completion of payment of any fine or restitution imposed, any person who has not previously been convicted of any other felony shall automatically be restored any civil rights which were lost or suspended by the conviction. A.R.S. § 13-912(A). Further, a person who has been discharged from probation may have any civil rights which were lost or suspended by the felony conviction restored. See A.R.S. § 13-905 (B).

III. Argument

Defendant realizes he made a serious mistake when he committed the current offense. He accepted responsibility and pled guilty. As far as counsel is aware, this case represents the only adult criminal convictions Mr. Danielian has suffered during his lifetime. He has complied with and completed all the terms of his probation.

As described above, Mr. Danielian has remained law-abiding since committing the current offenses. Additionally, Mr. Danielian has the support of family and friends and presents virtually no risk to re-offend. Mr. Danielian has demonstrated he is a stable, contributing member of society. Removal of this conviction from Mr. Danielian record will enable him to put this in his past and move on with his life. Based on his exceptional performance thus far, Counsel respectfully requests that the Court set aside the judgment of guilty pursuant to A.R.S. § 13-907.

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

IV. Conclusion

For the foregoing reasons, Defendant Kamo Danielian respectfully requests that this Court set aside his judgments of conviction pursuant to A.R.S. § 13-907, to restore his civil rights pursuant to A.R.S. § 13-912, and restore his right to possess or carry a gun or firearm pursuant to A.R.S § 13-905.

RESPECTFULLY SUBMITTED this 8th day of March, 2016.

MAASEN LAW FIRM

/s/ Scott A. Maasen
Scott A. Maasen
Attorneys for Defendant

Original of the foregoing via e-filing system
this 8th day of March, 2016, to:

Clerk of the Court
MARICOPA COUNTY SUPERIOR COURT
201 W. Jefferson St.
Phoenix, Arizona 85003

Copies of the foregoing via e-filing system
this 8th day of March, 2016, to:

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: */s/ Courtney R. Sullivan #032129*

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	Case No. CR2014-158850-001 DT **ORDER SETTING ASIDE JUDGMENT, RESTORING DEFENDANT'S CIVIL RIGHTS AND RESTORING DEFENDANT'S RIGHT TO POSSESS FIREARMS PURSUANT TO A.R.S §§ 13-907, 13-912 AND 13-905**

A Motion to Set Aside Judgment/Restore Civil Rights/Restore Right to Possess Firearms having been filed by the Defendant, with good cause appearing;

IT IS HEREBY ORDERED that Defendant Kamo Danielian shall receive a full restoration of his civil rights, including his right to possess a firearm, pursuant to A.R.S. §§ 13-905 and 13-912.

IT IS FURTHER ORDERED setting aside Defendant's judgment of conviction pursuant to A.R.S. § 13-907. Defendant's judgment of guilt as well as any felony information, indictment or other accusation underlying the judgment of guilt are hereby dismissed and Defendant is released from all penalties and disabilities resulting from her conviction in the above captioned cause.

DATED this ____ day of _____, 2016.

_____
JUDGE OF THE SUPERIOR COURT

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

COPIES of the foregoing mailed this
_____ day of _____, 2016 to:

Scott A. Maasen
MAASEN LAW FIRM
8707 E. Vista Bonita Dr., Ste. 230
Scottsdale, AZ 85255
Attorneys for Defendant

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: _____

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

3/8/16 FILED 10:30 Am
MICHAEL K. JEANES, Clerk
By J. Eddens, Deputy

STATE OF ARIZONA
Plaintiff,
VS.
KAMO DANIELIAN
Defendant,

Case Number:
CR2014-158850-001

NOTICE

The Court has received Defendant's Application for:

Applied For:

No	Motion for Reconsideration
Yes	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	Vacating the judgment of guilt and dismissing the charges against the Defendant as stated in the application herein.

This Application will be considered on or after the date of Monday, April 11, 2016
This is not a hearing. The application is ruled upon in a closed session and no appearance is required. The parties will be notified by mail upon ruling.

DATED this day, Wednesday, March 09, 2016

Master Calendar Commissioner, Judge Pro Tem of the Superior Court

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
R. Montoya, Deputy
3/10/2016 3:11:53 PM
Filing ID 7258527

Maricopa County

Clerk of the Superior Court

Criminal Financial Obligations

Restoration of Civil Rights Information Sheet

Date: Wednesday, March 09, 2016
Case Name: Kamo Danielian
Case Number: CR2014-158850-001

Court records reflect the following debts:

Restitution Amount:	$	0.00
Probation Fees Amount:	$	0.00
Fine Base Amount:	$	0.00
Fine Surcharge:	$	0.00
Reimbursement Amount:	$	0.00
Time Payment Amount:	$	0.00
Probation Assessment:	$	0.00

OTHER Fees:

County Collections Fee:	$	0.00
Interest Due as of this date:	$	0.00
_____	$	0.00
_____	$	
_____	$	
_____	$	
Grand Total:	$	0.00

MICHAEL K. JEANES, CLERK
BY DEP
FILED

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY 16 MAY 11 PM 2:27

State of Arizona **Plaintiff,**	)	**Case Number:**
vs.	)	**CR2014-158850-001**
Kamo Danielian **Defendant**	)	**ORDER**

The Court has received Defendant's Application, given proper notice and considered any response filed by the State.

IT IS ORDERED:

Applied For:	Granted	Denied	N/A	
No	☐	☐	☐	Motion for Reconsideration
Yes	☒ No Civil Rights Lost – Misdemeanor	☐	☐	Restoring any and all civil rights to the defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	☒ No Firearm Rights Lost – Misdemeanor	☐	☐	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	☐	☒	☐	Vacating the judgment of guilt and dismissing the charges against the Defendant as stated in the application herein.

Reason for denial: Due to the recent discharge from probation, IT IS ORDERED denying Defendant's Application. Additional time(at least 2 years) is required to pass since the defendant's discharge from probation for the Court to make a decision as to whether defendant's lifestyle has changed that would warrant setting aside the judgment. In the future, if the Defendant would like the Court to consider an Application To Set Aside the Judgment, Defendant needs to provide information, by way of letters and supporting documents, to the Court as to how his life has changed and why he deserves to have the judgment set aside. Without this proof, the Court cannot determine if the defendant has changed his lifestyle.

DONE this 6th day of May, 2016.

Phemonia L. Miller

PHEMONIA L. MILLER
COMMISSIONER/JUDGE PRO TEM

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
S. Kennow, Deputy
6/28/2017 12:39:24 PM
Filing ID 8454334

Scott A. Maasen
Arizona State Bar No. 018073
MAASEN LAW FIRM
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
office@maasenlaw.com
480-778-1500 (Tel)
480-778-0514 (Fax)
Attorneys for Defendant

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	Case No. CR2014-158850-001 DT **APPLICATION TO SET ASIDE JUDGMENT / RESTORE CIVIL RIGHTS / RESTORE RIGHT TO POSSESS FIREARM PURSUANT TO A.R.S. §§ 13-907, 13-912 AND 13-905**

Defendant Kamo Danielian, by and through undersigned counsel, hereby requests this Court to set aside his judgment of guilt, restore his civil rights and restore his right to possess or carry a gun or firearm pursuant to A.R.S. §§ 13-907, 13-912 and 13-905. This Motion is supported by the attached Memorandum of Points and Authorities.

RESPECTFULLY SUBMITTED this 28th day of June, 2017.

MAASEN LAW FIRM

/s/ Courtney R. Sullivan #032129 for:
Scott A. Maasen
Attorneys for Defendant

///
///

MEMORANDUM OF POINTS AND AUTHORITIES

I. Factual and Procedural History

On February 25, 2015, Mr. Danielian pled guilty to Solicitation to Commit Possession of Marijuana for Sale a Class 6 Felony, pursuant to a plea agreement. On the same date, Mr. Danielian was sentenced to nine (9) months of supervised probation. On May 8, 2015, Mr. Danielian was successfully discharged from probation. Mr. Danielian filed a previous motion to set aside the conviction and restore his civil rights and right to possess a firearm on December 15, 2015 but was denied due to Mr. Danielian having a past-due balance on probation fees. Mr. Danielian has completed payment of all of his fees as of this date. Mr. Danielian filed a subsequent motion on March 8, 2016, which was also denied due to close proximity to probation discharge date.

Since being discharged from probation, Mr. Danielian has graduated from Pharmacy School, where he earned his Pharm-D degree. Mr. Danielian has maintained employment throughout and since completing school, and is currently employed as a caregiver while he seeks employment as a pharmacist. Mr. Danielian is a responsible, hard-working caregiver with a compassionate, friendly attitude that his patients adore. (*See attached Character Letter from Oliver Fultz*). Mr. Danielian worked hard to graduate from pharmacy school and is focused and excited on beginning his new career as a pharmacist, though he will miss the clients and staff at Instant Care of Arizona.

Mr. Danielian has remained law-abiding, has fulfilled all obligations of this Court, and has completed alcohol education classes since his discharge from probation in this matter. Mr. Danielian was obviously very accountable and successful while on probation, as he was discharged at the request of the Adult Probation Department after serving just two months. The

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

APD also requested Mr. Danielian's charge be designated a misdemeanor at that time due to his lack of criminal history, acting out of character in the commission of the offense, and success with reporting to probation and paying fines in an expedient manner.

Mr. Danielian has strong family and community ties and is well-supported by his peers and loved ones. (*See attached character letters from family and neighbors*). Mr. Danielian remains close to his parents, brother, and grandparents, all of whom share their pride and admiration of Mr. Danielian with others. Mr. Danielian especially enjoys playing video games with his brother and taking walks with his grandfather.

Mr. Danielian has grown immensely as a person and as a professional in his career since the charges in this matter. Mr. Danielian has learned from his mistakes and worked hard to make up for them; he has cut back on the amount of drinking and going out, has excelled in school, and has overall gotten his life back on track. Mr. Danielian has set lofty goals for himself, including moving forward with his career and eventually owning a home. Mr. Danielian has so far faced difficulties in obtaining professional employment as a pharmacist due to his criminal record with this charge. Mr. Danielian has gone above and beyond to demonstrate that he is not the person who made the mistakes in this case, and will never find himself in this position again. Mr. Danielian has a rewarding future ahead of him and wants to begin his journey to that point by putting this case and his past regrets behind him.

II. Legal Standard

Every person convicted of a criminal offense may, upon fulfillment of the conditions of probation or sentence and discharge by the court, apply to the judge who pronounced sentence or such judge's successor in office to have the judgment of guilt set aside. A.R.S. § 13-907(A). If the judge grants the application, the judge shall set aside the judgment of guilt, dismiss the

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

accusations or information and order that the person be released from all penalties and disabilities resulting from the conviction. Id.

Upon completion of the term of probation, or upon absolute discharge from imprisonment, and upon the completion of payment of any fine or restitution imposed, any person who has not previously been convicted of any other felony shall automatically be restored any civil rights which were lost or suspended by the conviction. A.R.S. § 13-912(A). Further, a person who has been discharged from probation may have any civil rights which were lost or suspended by the felony conviction restored. See A.R.S. § 13-905 (B).

III. Argument

Mr. Danielian fully accepted responsibility for the choices he made and pled guilty to the charges in this matter. Mr. Danielian was sentenced to a rather short term of probation – 9 months – based on his character and lack of criminal history. Mr. Danielian complied with all requirements of sentencing and probation, and was discharged from probation after only 2 months due to his success, while having his offense designated a misdemeanor. The sentencing Court and APD clearly recognized Mr. Danielian's true character for a man who is smart, thoughtful, compassionate, and genuinely good. Mr. Danielian clearly acted out of character in the commission of the offense in this matter and has not demonstrated any similar behavior since. In fact, Mr. Danielian has done the opposite in working hard to move forward with his life in a positive direction and becoming a pharmacist.

As described above, Mr. Danielian has the support of family and friends and presents virtually no risk to re-offend. Mr. Danielian's career depends on the fact that he never make a similar mistake, and he knows he never will. Mr. Danielian has demonstrated he is a stable, contributing member of society with a positive outlook and bright future. Removal of this

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

conviction from Mr. Danielian record will enable him to put this in his past and move on with his life, and ideally to be able to obtain employment as a full-time pharmacist in the very near future. Based on his exceptional performance thus far, Counsel respectfully requests that the Court set aside the judgment of guilty pursuant to A.R.S. § 13-907.

IV. Conclusion

For the foregoing reasons, Defendant Kamo Danielian respectfully requests that this Court set aside his judgments of conviction pursuant to A.R.S. § 13-907, to restore his civil rights pursuant to A.R.S. § 13-912, and restore his right to possess or carry a gun or firearm pursuant to A.R.S § 13-905.

RESPECTFULLY SUBMITTED this 28th day of June, 2017.

MAASEN LAW FIRM

/s/ Courtney R. Sullivan #032129 for:
Scott A. Maasen
Attorneys for Defendant

Original of the foregoing via e-filing system
this 28th day of June, 2017, to:

Clerk of the Court
MARICOPA COUNTY SUPERIOR COURT
201 W. Jefferson St.
Phoenix, Arizona 85003

Copies of the foregoing via e-filing system
this 28th day of June, 2017, to:

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: */s/ Courtney R. Sullivan #032129*

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

STATE OF ARIZONA, Plaintiff, vs. KAMO DANIELIAN, Defendant.	)	Case No. CR2014-158850-001 DT **ORDER SETTING ASIDE JUDGMENT, RESTORING DEFENDANT'S CIVIL RIGHTS AND RESTORING DEFENDANT'S RIGHT TO POSSESS FIREARMS PURSUANT TO A.R.S §§ 13-907, 13-912 AND 13-905**

A Motion to Set Aside Judgment/Restore Civil Rights/Restore Right to Possess Firearms having been filed by the Defendant, with good cause appearing;

IT IS HEREBY ORDERED that Defendant Kamo Danielian shall receive a full restoration of his civil rights, including his right to possess a firearm, pursuant to A.R.S. §§ 13-905 and 13-912.

IT IS FURTHER ORDERED setting aside Defendant's judgment of conviction pursuant to A.R.S. § 13-907. Defendant's judgment of guilt as well as any felony information, indictment or other accusation underlyIng the judgment of guilt are hereby dismissed and Defendant is released from all penalties and disabilities resulting from her conviction in the above captioned cause.

DATED this ____ day of _____, 2017.

_____

JUDGE OF THE SUPERIOR COURT

Maasen Law Firm
8707 E. Vista Bonita Drive, Suite 230
Scottsdale, AZ 85255
P: (480) 778-1500 / F: (480) 778-0514

COPIES of the foregoing mailed this
_____ day of _____, 2017 to:

Scott A. Maasen
MAASEN LAW FIRM
8707 E. Vista Bonita Dr., Ste. 230
Scottsdale, AZ 85255
Attorneys for Defendant

MARICOPA COUNTY ATTORNEY'S OFFICE
301 W. Jefferson St.
Phoenix, Arizona 85003

By: _____



SCOTTSDALE TREATMENT INSTITUTE

CERTIFICATE OF COMPLETION

Kamo Danielian

has completed
16 hours of Level II
Alcohol and Drug Education

20th May 2016

Whitedove Ballogg, Counselor

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
A. James, Deputy
6/30/2017 4:11:54 PM
Filing ID 8462762

Maricopa County

Clerk of the Superior Court

Criminal Financial Obligations

Restoration of Civil Rights Information Sheet

Date: Friday, June 30, 2017
Case Name: KAMO DANIELIAN
Case Number: CR2014-158850-001

Court records reflect the following debts:

Restitution Amount:	$ 0.00
Probation Fees Amount:	$ 0.00
Fine Base Amount:	$ 0.00
Fine Surcharge:	$ 0.00
Reimbursement Amount:	$ 0.00
Time Payment Amount:	$ 0.00
Probation Assessment:	$ 0.00

OTHER Fees:

County Collections Fee:	$ 0.00
Interest Due as of this date:	$ 0.00
_____	$
_____	$
_____	$
_____	$
_____	$
_____	$
_____	$
_____	$
_____	$
Grand Total:	$ 0.00

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

MICHAEL K. JEANES, CLERK
DEP
M. Hernandez
M. HERNANDEZ, FILED
17 JUL -3 PM 1:24

STATE OF ARIZONA
Plaintiff,
VS.
KAMO DANIELIAN
Defendant,

Case Number:
CR2014-158850-001

NOTICE

The Court has received Defendant's Application for:

Applied For:

No	Motion for Reconsideration
Yes	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	Vacating the judgment of guilt and dismissing the charges against the Defendant as stated in the application herein.

This Application will be considered on or after the date of Wednesday, August 02, 2017
This is not a hearing. The application is ruled upon in a closed session and no appearance is required. The parties will be notified by mail upon ruling.

DATED this day, Wednesday, June 28, 2017

Master Calendar Commissioner, Judge Pro Tem of the Superior Court

MICHAEL K. JEANES, CLERK
BY A Trimble DEP
FILED
SEP 23 PM 3:00

THE SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

STATE OF ARIZONA
Plaintiff,
VS.
KAMO DANIELIAN
Defendant,

Case Number:
CR2014-158850-001

ORDER

The Court has received Defendant's Application, given proper notice and considered any response filed by the State.

IT IS ORDERED:

Applied For:	Granted	Denied	NA:	
No	☐	☒	☐	Motion for Reconsideration
Yes	☒	☐	☐	Restoring any and all civil rights to the Defendant which were lost or suspended as a result of the conviction as stated in the application herein.
Yes	☒	☐	☐	Restoring to the Defendant the right to possess a firearm which was lost or suspended as a result of the conviction as stated in the application.
Yes	☒	☒	☐	Setting aside the judgment of guilt, dismissing the accusations or information and releasing the Defendant from all applicable penalties and disabilities resulting from the conviction.

Automatic pursuant to 13-912 and designated a misdemea

Reason for denial:

DONE this 23 day of September, 2017

Judge of the Superior Court

HONORABLE BARBARA L. SPENCER
MARICOPA COUNTY SUPERIOR COURT

22

23

24

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
775-850-1440
bop.nv.gov

Nevada
(For locations located in the State of Nevada)
PHARMACYAPPLICATION
INFORMATION AND CHECKLIST

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Please understand we cannot and will not accept incomplete applications. Review the application and return all required fees and documentation with the completed application.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please note the application/documentation deadline date is on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications will be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, the application will be returned.

For a location or name change of an out-of-state pharmacy, we only require notification in writing. A new application is only required if changing ownership of 50% or greater.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP
You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

- Complete all required pages of the application. Must be original signature(s), no copies or stamps.

- Registration fee of $500.00. This fee is non-refundable and non-transferable. The fee is payable by money order or cashier's check only, we do not accept personal checks, business checks, cash or credit cards. If the application is received with a personal, business check or cash, it will be returned and will delay the processing of the application. Fee made payable to: Nevada State Board of Pharmacy

- Statement of Responsibility. This is page 10 included with the application

- Statement of Responsibility - Managing Pharmacist – (2 pages) The managing pharmacist must be registered with the Nevada State Board of Pharmacy and live in Nevada. Pages 11a and 11b.

- Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate of Corporate status is obtained from the Secretary of State's office in the State where incorporated. This Certificate of Corporate status must be dated within the last 6 months.

- Addendum to Pharmacy Application – Internet. This addendum is required if you will be providing internet services. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

REQUIRED INFORMATION FOR ALL TYPES OF OWNERSHIP

An application for Nevada pharmacy requires Board approval. Upon receipt of the completed application, documentation and fee, your application can be placed on the agenda of the next regularly scheduled Board meeting. The current board meeting schedule is available on the website under the "Calendar of Upcoming Boards & Committee Meetings".

http://bop.nv.gov/board/ALL/Board_Meeting_Schedule/

Appearance(s) at the board meeting may be required. If you have never operated a pharmacy in Nevada before, you will be required to appear at a scheduled board meeting. If an appearance is required, you will be informed by way of confirmation letter two (2) weeks prior to the meeting. Otherwise assume an appearance will not be necessary.

If the application is approved at the scheduled meeting a letter with the information needed to schedule the required pre-opening inspection will be mailed within 15 days from the date of the meeting

Any change of ownership and/or location change, will require a new application and $500.00 fee. If the address changes, a pre-opening inspection will be required.

Upon board approval and satisfactory inspection a license will be issued and mailed within 15 days from the date of the inspection. A license number will not be provided until the inspection has been completed.

This license is renewed in October of even numbered years, no matter when the license is issued. Fees are not pro-rated.

Please access the applicable laws on the website under "Nevada Statues & Regulations" tab.

If you have any questions, contact the licensing specialist in the Reno office at (775) 850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

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

APPLICATION FOR NEVADA PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐New Pharmacy or ☐Ownership Change (Provide current license number if making changes: PH_____
Check box below for type of ownership and complete all required forms. **If LLC use Non Public Corporation or Partnership.

☐ Publicly Traded Corporation – Pages 1,2,3,10,11a&b
☐ Non Publicly Traded Corporation – Pages 1,2,4,10,11a&b
☐ Partnership - Pages 1,2,6,10,11a&b
☐ Sole Owner – Pages 1,2,8,10,11a&b

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: _____

Physical Address: _____

City:_____ State:_ Zip Code: _____ Telephone:_

_____ Fax:_____ Toll Free Number:_____

_____ E-mail:_____

Website: _____

Managing Pharmacist:_____ License Number: _____

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☐	☐ Retail	☐	☐ Off-site Cognitive Services
☐	☐ Hospital (# beds____)	☐	☐ Parenteral
☐	☐ Internet	☐	☐ Parenteral (outpatient)
☐	☐ Nuclear	☐	☐ Outpatient/Discharge
☐	☐ Ambulatory Surgery Center	☐	☐ Mail Service
☐	☐ Community	☐	☐ Long Term Care
☐	☐ Other: _____	☐	☐ Sterile Compounding
		☐	☐ Non Sterile Compounding
All boxes must be checked		☐	☐ Mail Service Sterile Compounding
For the application to be complete		☐	☐ Other Services: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☐

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☐

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☐

If the answer to question 1 through 5 is “yes”, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

_____
Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____
Print Name of Authorized Person Date

Board Use Only Date Processed:_____ Amount: _____

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City:_____State:_____Zip: _____

Telephone:_____Fax: _____

Contact Person: _____

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Mailing Address: _____

City:_____State:_____Zip: _____

Telephone:_____Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a)_____
Name Business Address

b)_____
Name Business Address

c)_____
Name Business Address

d)_____
Name Business Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

List any physician shareholders and percentage of ownership.

Name:_____%:_____

Name:_____%: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a non publicly traded corporation continued

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP. All persons listed as a partner must accurately complete a personal history record form.

Type of Partnership: General_____ Limited _____

List names of 4 largest partners and percentage of ownership:

Name:_____%:_____

Name:_____%:_____

Name:_____%:_____

Name:_____%: _____

Partnership Name: _____

Mailing Address: _____

City, State Zip Code: _____

Telephone Number:_____Fax Number: _____

Contact Person: _____

List any physician shareholders and percentage of ownership.

Name:_____%:_____

Name:_____%:_____

Name:_____%: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a partnership continued

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record for each stockholder. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

APPLICATION FOR NEVADA PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City:_____ State:_____ Zip Code: _____

Telephone:_____ Fax: _____

List any physician shareholders and percentage of ownership.

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Include with the application for a sole owner

Designated representative form. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

The designated representative (as defined in NAC 639.5005) needs to complete the form, submit the required 6000 hours of employment with a pharmacy or wholesaler and will be required to take and pass an exam on Nevada law prior to the license being issued. Upon receipt of the completed application, a law book and requirements for taking the exam will be provided to the designee. If the designated representative is the managing pharmacist, the law test is not required.

Complete the personal history record. Download the form from the website under the "Applications/Services" tab. The forms are available under the documents of all types of businesses. Must be an original signature, no copies or stamps.

STATEMENT OF RESPONSIBILITY – Nevada Pharmacy
FOR Corporations, Partnership or Sole Owners

I,_____

Responsible Person of _____

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

_____

Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____

Print Name of Authorized Person Date

Managing Pharmacist

Pharmacist Name:_____ License #: _____

Pharmacy Name: _____

As a managing pharmacist of the above referenced pharmacy, I understand within 48 hours after I report for duty as the managing pharmacist, I shall cause an inventory of all controlled substances of the pharmacy according to the method prescribed by the provision of 21 CFR Part 1304; and cause a copy of the inventory to be on file at the pharmacy.

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be the subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am managing pharmacist.

I understand that if I cease to be managing pharmacist of the above named pharmacy I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

	Yes	No
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☐
1. been charged, arrested or convicted of a felony or misdemeanor in any state?	☐	☐
2. been the subject of a board citation or an administrative action whether completed or pending in any state?	☐	☐
3. had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	☐	☐

If you marked YES to any of the numbered questions above, please include the following information

Board Administrative Action: State: _____ Date: _____ Case #: _____

And/or Criminal Action: State: _____ Date: _____ Case #: _____

County _____ Court: _____

PHARMACY MANAGER'S RESPONSIBILITIES
(PHARMACY MANAGER TO READ, DATE, AND SIGN THIS SECTION)

1. Insure the pharmacy is operated in accordance with all state and federal laws and regulations. (NRS 639.220)

2. Maintain all outdated, mislabeled or adulterated medications in an isolated area separated from medications for current use. (NRS 639.282, NAC 639.510, NAC 639.473<2>)

3. Notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. (NAC 639.540)

4. Maintain documentation of pharmacy technician in-service records or technician in training daily logs available for inspection at the pharmacy. (NAC 639.254<2>)

5. A complete controlled substance inventory must be taken every 2 years and whenever there is a pharmacy manager change (must be completed within 48 hours). (CFR 1304.11, NAC 453.475)

6. Report any loss or theft of controlled substances to the Nevada State Board of Pharmacy, Department of Public Safety, and Drug Enforcement Administration within 10 days of the occurrence. (NRS 453.568)

7. Maintain prescription records/logs for 2 years (2 years from last fill date for original paper prescription). NRS 639.236, NAC 453.480)

8. Maintain records of sales to practitioners or other licensed providers as invoices for 2 years. (NRS 639.268, NAC 453.485)

9. Maintain invoice records separated as required for 2 years. (NRS 454.286, NAC 639.487)

I have read all questions, answers and statements and know the content thereof. I hereby certify, under penalty of perjury, that the information furnished on this application is true, accurate and correct.

_____ _____

Signature Date

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521
775-850-1440
bop.nv.gov

OUT-OF-STATE
(For locations shipping to the State of Nevada
PHARMACYAPPLICATION
INFORMATION AND CHECKLIST

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Please understand we cannot and will not accept incomplete applications. Review the application and return all required fees and documentation with the completed application.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please note the application/documentation deadline date is on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications will be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, the application will be returned.

For a location or name change of an out-of-state pharmacy, we only require notification in writing. A new application is only required if changing ownership of 50% or greater.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP
You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

Complete all required pages of the application. Must be original signature(s), no copies or stamps.

Statement of Responsibility. This is page 8 included with the application

Registration fee of $500.00. This fee is non-refundable and non-transferable. The fee is payable by money order or cashier's check only, we do not accept personal checks, business checks, cash or credit cards. If the application is received with a personal, business check or cash, it will be returned and will delay the processing of the application. Fee made payable to: Nevada State Board of Pharmacy

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate of Corporate status is obtained from the Secretary of State's office in the State where incorporated. This Certificate of Corporate status must be dated within the last 6 months.

Letter of good standing from the state or regulatory board in which your company is located. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*. An original separate letter from the state or regulatory board also acceptable.

Copy of current registration or license for the pharmacy in the state of residence.

Copy of recent inspection.

AFFIDAVIT for Out-of-State Pharmacy License – Blank form is included.

Statement of Responsibility for Pharmacies Located Outside of Nevada – Blank form included

Addendum to Pharmacy Application – Internet. This addendum is required if you will be providing internet services. Download the form from the website under the "Services/Applicants" tab. The forms are available under the *documents for all types of businesses*.

Copy of Current DEA Registration (if applicable)

REQUIRED INFORMATION FOR ALL TYPES OF OWNERSHIP

An application for an out-of-state pharmacy requires Board approval. Upon receipt of the completed application, documentation and fee, your application will be placed on the agenda of the next regularly scheduled Board meeting. The current board meeting schedule is available on the website under the "Calendar of Upcoming Boards & Committee Meetings".

AN APPEARANCE AT THE BOARD MEETING WILL BE REQUIRED, IF THE PHARMACY INTENDS TO SHIP PARENTERAL PRODUCTS, INCLUDING STERILE COMPOUNDED DRUGS INTO NEVADA. Nevada Administrative Code (NAC) 639.215 provides, "An applicant for a license to operate a pharmacy in the State of Nevada must appear before the board in support of the application and must received instructions relative to the pharmacy laws, if the applicant . . .(c) is applying for the licensure of a pharmacy located outside the state that will be shipping compounded parenteral products into this state.

The purpose is to insure firms will provide a continuum of home parenteral care which has frequently been absent with contract providers of parenteral pharmaceutical products from out-of-state. Our regulation in part will require:

1. A pharmacist, practitioner and nurse must be available at all times for immediate assistance to the patient;
2. The pharmacy must have access to orders for the medication, laboratory tests and other patient treatments; and
3. Documentation that patient assessment has been performed.

Your presence before the board can describe how these services are available and how you fulfill the requirements of the regulations.

The board has a legal right to require an appearance at a schedule board meeting. If an appearance is **required**, your company will be notified in writing two (2) weeks prior to the meeting.

If you check off-site cognitive services on the application, Nevada Administrative Code 639.4916 requires “A pharmacist who is employed by an off-site pharmaceutical service provide to provide remote chart order processing services to a hospital or correctional institution pursuant to NAC 639.4915 must (a) Be licensed to practice in Nevada.” Provide name and Nevada pharmacist license number. This does not have to be the managing pharmacist.

A license is usually issued and mailed within 15 days from the board meeting date, if approved.

This license is renewed in October of even numbered years, no matter when the license is issued. Fees are not pro-rated.

Please access the applicable laws on the website under “Nevada Statues & Regulations” tab.

If you have any questions, contact the licensing specialist in the Reno office at (775) 850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

*☐New Pharmacy or ☐**Ownership Change** (Provide current license number if making changes: **PH**_____*
Check box below for type of ownership and complete all required forms.
☐ Publicly Traded Corporation – Pages 1,2,3,7 *☐ Partnership - Pages 1,2,5,7*
☐ Non Publicly Traded Corporation – Pages 1,2,4,7 *☐ Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: _____

Physical Address: _____

Mailing Address: _____

City:_____ State:_____ Zip Code: _____

Telephone:_____ Fax: _____

Toll Free Number:_____(Required per NAC 639.708)

E-mail:_____ Website: _____

Managing Pharmacist:_____ License Number: _____

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No		Yes/No	
☐	Retail	☐	Off-site Cognitive Services
☐	Hospital (# beds_____)	☐	Parenteral **
☐	Internet	☐	Parenteral (outpatient)
☐	Nuclear	☐	Outpatient/Discharge
☐	Ambulatory Surgery Center	☐	Mail Service
☐	Community	☐	Long Term Care
☐	Other: _____	☐	Sterile Compounding **
		☐	Non Sterile Compounding
All boxes must be checked		☐	Mail Service Sterile Compounding **
For the application to be complete		☐	Other Services: _____

****If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☐

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☐

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☐

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☐

If the answer to question 1 through 5 is “yes”, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

_____
Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____
Print Name of Authorized Person Date

Board Use Only Date Processed:_____ Amount: _____

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City:_____State:_____Zip: _____

Telephone:_____Fax: _____

Contact Person: _____

If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

Date of Incorporation: _____

Registration number issued: _____

Stock Exchange: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Must be included with the application for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Mailing Address: _____

City:_____State:_____Zip: _____

Telephone:_____Fax: _____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a)_____
Name Address

b)_____
Name Address

c)_____
Name Address

d)_____
Name Address

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name:_____%:_____

Name:_____%: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

Must be included with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP

General _____ Limited _____

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip Code: _____

Telephone Number: _____ Fax Number: _____

Contact Person: _____

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
_____	_____	_____
_____	_____	_____

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday _____ am _____ pm Saturday _____ am _____ pm

Sunday _____ am _____ pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City:_____ State:_____ Zip Code: _____

Telephone:_____ Fax: _____

List any physician shareholders and percentage of ownership.

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %:_____

Name:_____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday_____am _____pm Saturday _____am _____pm

Sunday _____am _____pm 24 Hours _____

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I,_____

Responsible Person of _____

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

_____

Original Signature of Person Authorized to Submit Application, no copies or stamps

_____ _____

Print Name of Authorized Person Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF_____)
) ss.
_____COUNTY)

I,_____, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the _____ for _____ (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out- of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I,_____, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

_____
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
___day of_____, 20___.

_____
NOTARY PUBLIC

Transmitting Controlled Substance Prescription Data

Pursuant to NAC 639.926, pharmacies and dispensing practitioners that dispense controlled substances listed in schedule II, III or IV are required to submit data to the Board each week; however, we highly encourage dispensers to submit data on a nightly basis when possible. If a dispenser has not dispensed any controlled substances for the required time period, the dispenser is required to submit a zero reporting transmission.

The Nevada State Board of Pharmacy contracts with Appriss to manage the data collection for the Nevada Prescription Monitoring Program (PMP). For information to register and submit data please visit: http://bop.nv.gov. Click Links, click Prescription Monitoring Program, click Dispenser Guide.

If you have any questions or need additional information, please email: pmp@pharmacy.nv.gov

NEVADA STATE BOARD OF PHARMACY

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

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (06/24/2021)

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Approval of this application is required to conduct a pharmacy in Nevada or for a pharmacy located in another state to ship pharmaceutical products into Nevada. Any change of name, ownership, or location will require a new application and $500.00 fee. A license to conduct a pharmacy is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.

Print and mail the completed application with a **non-refundable fee of $500.00** paid for by credit or debit card or a check made payable to the **Nevada State Board of Pharmacy**. Credit and debit card payments are charged a **5% processing fee**. Send the completed application to the address indicated on top of this application.

Please ensure all requirements of the application are completed before submission. The deadline date for an application to be considered during a board meeting is posted on our website. If a completed application is not received by our office by the deadline, the application will not be considered until the next scheduled board meeting. **Please note that an application received just prior to the deadline date does not guarantee placement on the board agenda.** For application deadlines and meeting schedule visit www.bop.nv.gov.

Please note:

- An appearance at a board meeting may be required. If an appearance is required, you will be informed by letter two (2) weeks prior to the meeting.
    - If an applicant who is required to appear before the board is:
        - A partnership, all partners must appear. NAC 639.215
        - A corporation, a designated representative of the corporation must appear. If the designated representative is not an officer of the corporation, a letter authorizing him or her to appear on behalf of the corporation that is signed by an officer of the corporation must be submitted with the application. Documentation of the status of the person signing the letter of authorization must be submitted with the application. NAC 639.215
        - A pharmacy performing sterile compounding, a person with direct knowledge of compounding procedures.

- For Nevada pharmacies, upon approval of the application a pre-opening inspection will be required. Information regarding the pre-opening inspection will be provided to you after the approval of your application.

- Once an application is approved, the pharmacy receives a satisfactory pre-opening inspection (for Nevada pharmacies), and all other requirements of the board have been completed, a license will be issued.

- The license must be renewed in **October of even numbered years** despite when the original license was issued. Fees ARE NOT prorated.

- Nevada statutes and regulations can be accessed at www.bop.nv.gov

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

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

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (06/24/2021)

Where is the facility located?
☐ Nevada
☐ Out-of-State

Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change*	* If making a change, provide current license number: PH_____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9, 10, 11) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9, 10, 11) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9, 10, 11) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9, 10, 11)

Section 1: General Information

Pharmacy Name: _____

Physical Address: _____

City: _____ State: _____ Zip: _____

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: _____

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name: _____

Type of Pharmacy (check all applicable)	**Services the Pharmacy will Provide (check all applicable)**
☐ Retail/Community	☐ Retail/Community
☐ Hospital (# beds _____)	☐ Non-sterile Compounding
☐ Internet	☐ Sterile Compounding
☐ Nuclear	☐ Mail-Order Service
☐ Other:	☐ Off-site Cognitive Services
	☐ Long Term Care
	☐ Hospital
	☐ Other:

Days of Operation						
☐ Monday	☐ Tuesday	☐ Wednesday	☐ Thursday	☐ Friday	☐ Saturday	☐ Sunday

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

Section 3: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the _____ (title) for _____ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.

_____

Print Name of Authorized Person

_____ _____

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

Section 9: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, _____ hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the _____ (title) for _____ (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

Section 10: Managing Pharmacist Acknowledgement, Professional/Personal History - MUST BE COMPLETED by the MANAGING PHARMACIST for NEVADA PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: _____ Pharmacist License #: _____

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

_____ I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

_____ I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

_____ I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

_____ I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

_____ I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	**Yes**	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	**State:**	**Date:**	**Case #:**

Criminal Action:	**State:**	**Date:**	**Case #:**	**County:**	**Court:**

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

_____ _____

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

Section 11: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	**Publicly Traded**	**Non-publicly Traded**	**Partner-ship**	**Sole Owner**
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** o **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/. NAC 639.5005		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f)	✓	✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a)	✓	✓	✓	✓
• **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g)	✓	✓	✓	✓
• **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)**	✓	✓	✓	✓
• **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)**	✓	✓	✓	✓
• **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

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

_____

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

_____ _____

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

Board Use Only	Date Received: _____ Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

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

• Web Page: bop.nv.gov

Applicant Name: _____

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to **Nevada State Board of Pharmacy**. Credit Cards are charged a 5% processing fee		
Credit Type: ☐ Visa ☐ MasterCard ☐ Discover ☐ American Express	**Credit Card #:** __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	
Expiration Date: __ __/__ __ (MM/YY	**CVV** (3 digits on back of card): _____	**License Amount**: $_____
Name on Card: _____		
Billing Address: _____ _____ _____		

25

NEVADA STATE BOARD OF PHARMACY

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

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Rev (06/24/2021)

This application cannot be returned by fax or email.
We must have an original signature and fee to process.

Approval of this application is required to conduct an Ambulatory Surgical Center or a Recovery Center in Nevada. Any change of name, ownership, or location will require a new application and $500.00 fee. A license to conduct an Ambulatory Surgical Center or a Recovery Center is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.

Print and mail the completed application with a **non-refundable fee of $500.00** paid for by credit or debit card or a check made payable to the **Nevada State Board of Pharmacy**. Credit and debit card payments are charged a **5% processing fee**. Send the completed application to the address indicated on top of this application.

Please ensure all requirements of the application are completed before submission. The deadline date for an application to be considered during a board meeting is posted on our website. If a completed application is not received by our office by the deadline, the application will not be considered until the next scheduled board meeting. **Please note that an application received just prior to the deadline date does not guarantee placement on the board agenda.** For application deadlines and meeting schedule visit www.bop.nv.gov.

Please note:

- An appearance at a board meeting may be required. If an appearance is required, you will be informed by letter two (2) weeks prior to the meeting.
- Upon approval of the application a pre-opening inspection will be required. Information regarding the pre-opening inspection will be provided to you after the approval of your application.
- Once an application is approved, the facility receives a satisfactory pre-opening inspection and all other requirements of the board have been completed, a license will be issued.
- The license must be renewed in **October of even numbered years** despite when the original license was issued. Fees ARE NOT prorated.
- Nevada statutes and regulations can be accessed at www.bop.nv.gov.

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

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

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (06/24/2021)

Type of Facility		
☐ Ambulatory Surgical Center (ASC) ☐ Recovery Center (RC)		
Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New ASC/RC ☐ Ownership Change* ☐ Location Change * ☐ Name Change*	* If making a change, provide current license number: _____	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8) ☐ Non-Publicly Traded (complete sections 1, 2, 4, 7,8) ☐ Partnership (complete sections 1, 2, 5, 7, 8) ☐ Sole Owner (complete sections 1, 2, 6, 7, 8)

Section 1: General Information

ASC/RC Name:_____

Physical Address: _____

City: _____ State: _____ Zip: _____

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Email: _____ Website _____

Nevada Business License # _____

Employed/Contracted Pharmacist Name: _____ NV Pharmacist License #: _____

Medical Director Name: _____

Days of Operation

☐ Monday	☐ Tuesday	☐ Wednesday	☐ Thursday	☐ Friday	☐ Saturday	☐ Sunday

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

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: _____ Pharmacist License #: _____

As the employed/contracted pharmacist, for (ASC/RC Name): _____:

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

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

_____ _____

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted) Date

Section 8: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** o **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

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

_____

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

_____ _____

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

Board Use Only	Date Received: _____ Amount: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

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

• Web Page: bop.nv.gov

Applicant Name: _____

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to **Nevada State Board of Pharmacy**. Credit Cards are charged a 5% processing fee		
Credit Type: ☐ Visa ☐ MasterCard ☐ Discover ☐ American Express	**Credit Card #:** __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __	
Expiration Date: __ __/__ __ (MM/YY	**CVV** (3 digits on back of card): _____	**License Amount**: $_____
Name on Card: _____		
Billing Address: _____ _____ _____		

26

27

EXECUTIVE SECRETARY REPORT – July 14-15, 2021

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **CHANGE OF ADDRESS BUSINESS LIST**
- **STAFF ACTIVITIES**
  - Meetings with Other Health Care Boards
  - COVID-19
  - NABP National Meeting
- **REPORT TO BOARD**
  - Legislative Update
- **BOARD RELATED NEWS**
- **ACTIVITIES REPORT**
  - Covid Vaccine update

TEMPORARY LICENSES
(Issued since last board meeting)

Renown Health Pharmacy

James Milner

Curtis Applegate

Caren-Mai Azurin

CVS

Shahrzad Mohammadi

Wayne Shuler

Wal-Mart

David Flint

Encompass Health Rehab Hospital

Lori Arnold

Banner Churchill Community Hospital

Andrew Bottorff

Nevada

Change of Address Business List

(Since Last Board Meeting)

No Address change applications have been submitted since last board meeting.

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
639.NEW – Delivery of a Prescription to Practitioner	01/16/20	01/21/20	R009-20	02/27/20	06/09/20	06/03/21	06/15/21	
639.220 - licensing and regulation of a facility to dispense controlled substances and dangerous drugs if the facility is licensed by the State Board of Health (recovery centers)	03/19/20 – postponed to 06/03/20	6/16/20	R085-20	09/17/20	10/22/20 12/03/20	01/13/21	01/29/21	04/14/21
639.NEW - licensing and regulating the practice of pharmacy (appearance requirements)	03/19/20	3/24/20	R041-20	05/14/20	06/09/20	07/16/20	07/22/20	08/26/20
453.550 – Deschedule Epidiolex	06/03/20	6/16/20	R090-20 R073-19	07/30/20	09/11/20	10/15/20	10/28/20	12/29/20
639.NEW – CS Electronic Transmission Exemption	06/03/20	6/16/20	R083-20	10/15/20	10/07/20	11/10/20	12/12/20	12/29/20
639.464 & 639.468 – P&T Committee vs CPA	06/03/20				Dave revising			
639.NEW – PT Administer Immunizations	07/16/20	07/21/20	R142-20	08/20/20	08/03/20	09/03/20	09/15/20	09/21/20
453.510 – Schedule I - Designer Benzos	07/16/20	07/21/20	R143-20	12/14/20	01/26/21	03/03/21	03/24/21	04/14/21
453.510 – Schedule II - Kratom	07/16/20	07/21/20	R144-20	12/14/20				
NAC 639.742, 639.743, 639.744. and 639.745: Dispensing Practitioners: shared inventory and centralized activities.	09/03/20 01/13/21	03/12/21	R007-21					

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.501 – Workplace Assessment Tool	10/15/20	10/21/20	R165-20					
NAC 639 Pharmacist Practice Location	10/15/20	10/21/20	R164-20					
NAC 639 – Cite and Fine for Misfilled Prescriptions	10/15/20	10/21/20	R166-20					
NAC 639.220 - Schedule of fees; medical interns and residents reduced fees	01/13/21	02/02/21	R003-21					
NAC 639.NEW Compounded Drugs (dispensing, supplying, furnishing)	01/13/21	01/20/21	R002-21					
NAC 639.715, 639.718, 639.720: Use of mechanical devices to dispense drugs	03/03/21 06/03/21	06/10/21	R013-21					
NAC 453: PMP Integration with electronic health records of practitioners	03/03/21	03/12/21	R008-21					
NAC 639: Reference Standards for Compounding	06/03/21	06/10/21	R012-21					
NAV 639: Hormonal Contraceptive Protocol	07/15/21							
NAC 639: Background Check RPH, PT, PTT; increase fees for investigation or issuance or renewal of a license as a manufacturer or wholesaler; application valid for one year; clarify licensing requirements for an outsourcing facility or	07/15/21							

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
euthanasia technician. (Senate Bill 408)								
NAC 453.510: Schedule I – Eutylone and fentanyl related substances.	07/15/21							
NAC 453.540: Schedule IV – lemborexant and Remimazolam.	07/15/21							
NAC 639: Allow pharmacists to dispense drugs approved the FDA for human immunodeficiency virus. (Senate Bill 325)	07/15/21							

From: Pam Schweitzer <pamela.schweitzer926@gmail.com>
Sent: Friday, June 11, 2021 11:37 AM
To: Carter, Al <acarter@nabp.pharmacy>
Cc: pharmacy@pharmacy.nv.gov
Subject: Feedback - Nevada BOP - Kudos

Al,

I was on a call this morning with public health folks and the person representing Nevada was raving about the Board of Pharmacy in Nevada - working with them was a game changer in addressing COVID-19 vaccine administration in their state.

I just wanted you to know - this is a model program nationally.

Pam

--
RADM (ret) Pamela Schweitzer, Pharm.D.
Former Assistant Surgeon General
10th Chief Pharmacist Officer, USPHS Commissioned Corps
e-mail: pamela.schweitzer926@gmail.com
(m) 480-285-8072

David Wuest

From: Pharmacy Board
Sent: Monday, June 14, 2021 10:27 AM
To: David Wuest; Yenh Long
Subject: Fw: Feedback - Nevada BOP - Kudos

From: Carter, Al <acarter@nabp.pharmacy>
Sent: Friday, June 11, 2021 11:57 AM
To: Pam Schweitzer
Cc: Pharmacy Board
Subject: RE: Feedback - Nevada BOP - Kudos

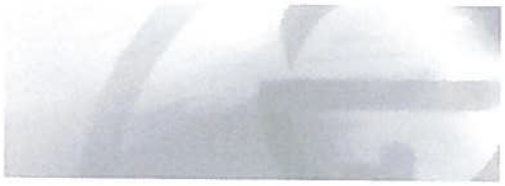
Thank you, Pam.

Kudos to Dave and team! They are doing some great things in Nevada and being very progressive in protecting public health.

Regards,
Al

Lemrey "Al" Carter, PharmD, MS., RPh
Executive Director/Secretary
847-391-4412

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | acarter@nabp.pharmacy



NABP | National Association of Boards of Pharmacy

www.nabp.pharmacy

NABP is an international nonprofit organization that supports and works with the state boards of pharmacy to protect the public's health.

28

28A

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – July 15, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.127; NRS 639.1371; NRS 639.170

A REGULATION relating to the practice of pharmacy; implementing the requirements of Senate Bill 408 requiring an applicant for registration as a pharmacist or pharmaceutical technician to undergo a criminal background check; increasing the fees for the investigation or issuance or renewal of a license as a manufacturer or wholesaler; providing that an application for any certificate, license or permit issued by the Board is only valid for 1 year after the date it is received by the Board unless the Board extends its period of validity; clarifying the licensing requirements for an outsourcing facility or euthanasia technician; and providing other matters properly relating thereto.

Section. 1. NAC 639.220 is hereby amended to read as follows:

1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist.....	Actual cost of the examination
For the investigation or registration of an applicant as a registered pharmacist.....	$180
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....	180
For the investigation or issuance of an original license to conduct a retail pharmacy.....	500
For the biennial renewal of a license to conduct a retail pharmacy.....	500
For the investigation or issuance of an original license to conduct an institutional pharmacy.....	500
For the biennial renewal of a license to conduct an institutional pharmacy.	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution.....	500
For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....	500
For the issuance of an original or duplicate certificate of registration as a registered pharmacist.....	50
For the biennial renewal of registration as a registered pharmacist.....	180
For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse).....	100
For the initial registration of a pharmaceutical technician or pharmaceutical technician in training.....	40

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training.....	40
For the investigation or registration of an intern pharmacist.....	40
For the biennial renewal of registration as an intern pharmacist.....	40
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....	80
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....	80
For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....	80
For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....	80
For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....	500
For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....	500
For the investigation or issuance of an original license to a manufacturer, ***outsourcing facility*** or wholesaler.....	~~***500***~~ ***1000***
For the biennial renewal of a license for a manufacturer, ***outsourcing facility*** or wholesaler.....	~~***500***~~ ***1000***
For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....	50
For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....	300
For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for each location where the practitioner will dispense controlled substances or dangerous drugs, or both.....	300
For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....	150
For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both.....	150

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

Ê is not required to pay the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.

6. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B), as that section existed on March 1, 2000, that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

➥ is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

Section. 2. NAC 639.240 is hereby amended to read as follows:

1. No person may perform the duties of a pharmaceutical technician until the person has been issued a certificate of registration.

2. An applicant for registration as a pharmaceutical technician must:

(a) Be 18 years of age or older;

(b) Be a high school graduate or the equivalent;

(c) Not have been convicted of any felony or a misdemeanor involving moral turpitude, dishonesty or the unlawful possession, sale or use of drugs;

(d) Have no history of drug abuse; ~~***and***~~

(e) ***Have complied with the requirements of NRS 639.1371(4); and***

(f) Have complied with one of the following requirements:

(1) The successful completion of a program of training for pharmaceutical technicians, including, but not limited to, a program of training offered by a postsecondary school, that is approved by the Board pursuant to NAC 639.256.

(2) Registration in another state as a pharmaceutical technician, if the requirements for registration in that state are equivalent to the requirements of this State, and the successful completion of at least 240 hours of employment as a pharmaceutical technician in a pharmacy in that state, which must be verified by the managing pharmacist of the pharmacy.

(3) If the state in which the applicant has been employed does not offer registration, licensure or certification as a pharmaceutical technician:

(I) The successful completion of at least 1,500 hours of experience in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371 during the 3 years immediately preceding the date on which his or her application was submitted;

(II) The successful completion of at least 350 hours of employment in a pharmacy in this State; and

(III) The acquisition of a written statement to the Board from the managing pharmacist of the pharmacy referred to in sub-subparagraph (II) stating that the applicant, during his or her employment, demonstrated competence to perform the tasks assigned to him or her.

➥ Such an applicant must register as a pharmaceutical technician in training before he or she completes the requirements of sub-subparagraph (II).

(4) The successful completion of at least 1,500 hours of training and experience as a pharmaceutical technician in training. A pharmaceutical technician in training may accumulate certified hours of training from each place of employment.

(5) The successful completion of a program of training for pharmaceutical technicians conducted by a branch of the Armed Forces of the United States, the Indian Health Service of the United States Department of Health and Human Services or the United States Department of Veterans Affairs.

(6) Certification by the Pharmacy Technician Certification Board or the National Healthcareer Association as a pharmacy technician if:

(I) The applicant successfully completes a program of training for pharmaceutical technicians conducted by a postsecondary school in another state;

(II) The program is accredited or otherwise approved by the appropriate regulatory authority in that state; and

(III) The applicant successfully completes at least 240 hours of employment as a pharmaceutical technician in training in a pharmacy in another state, which must be verified by the managing pharmacist of the pharmacy.

3. An applicant who attended a school outside the United States must submit to an organization which evaluates educational credentials a copy of the transcript of his or her academic record from that school for a determination of whether the grades the applicant received are substantially equivalent to the grades required for an applicant who attended a school, or a program of training for pharmaceutical technicians that is accredited by the American Society of Health-System Pharmacists, in the United States. The applicant must ensure that a copy of the organization's evaluation of the transcript is submitted to the Board.

4. Upon receipt of an application and the required fee, the Executive Secretary shall, unless he or she has good cause to deny the registration, issue a certificate of registration to the pharmaceutical technician.

Section. 3. NAC 639.5931 is hereby amended to read as follows:

A person who is required to submit a complete set of his or her fingerprints to the Board pursuant to NRS 639.500 or 639.505 or NAC 639.593 ***or section 3 of LCB File No. R040-20 or NRS 639.127(2) or NRS 639.1371(4) may*** submit the fingerprints electronically in a format prescribed by the Board.

Section. 4. Section 4 of LCB File NO. R040-20 is hereby amended to read as follows:

1. If a complete set of fingerprints from any person required to submit fingerprints pursuant to NRS 639.500 or 639.505 or NAC 639.593 or section 3 of LCB File No. R040-20 or NRS 639.127(2) or NRS 639.1371(4) is rejected by the Central Repository for Nevada Records of Criminal History, the person shall submit a second complete set of fingerprints and written permission authorizing the Board to forward the second complete set of fingerprints to the Central Repository for submission to the Federal Bureau of Investigation for its report. 2. If the second complete set of fingerprints of any person pursuant to subsection 1 is rejected by the Central Repository for Nevada Records of Criminal History, the Executive Secretary shall request a name-based background check of the person.

2. If the second complete set of fingerprints of any person pursuant to subsection 1 is rejected by the Central Repository for Nevada Records of Criminal History, the Executive Secretary shall request a name-based background check of the person.

Section. 5. NAC 639.5915 is hereby amended to read as follows:

An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:

1. Obtain a license from the Board ~~*as a manufacturer*~~ in accordance with NRS 639.100 and 639.233 ***by submitting an application on a form prescribed by the Board***;
2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
3. Comply with all the requirements of 21 U.S.C. § 353b.

Section. 6. NAC Chapter 639 is hereby amended by adding thereto a new section to read as follows:

1. As used in this section, unless the context otherwise requires, the term "euthanasia technician" has the meaning ascribed to it in NRS 638.005.

2. A euthanasia technician who wishes to possess or administer sodium pentobarbital pursuant to NAC 638.510 must apply to the Board on a form prescribed by the Board for a certificate of registration in accordance with NRS 453.226.

3. Registration pursuant to subsection 2 to possess or administer sodium is a revocable privilege, and no holder of such a certificate of registration acquires any vested right therein or thereunder.

Section. 7. NAC Chapter 639 is hereby amended by adding thereto a new section to read as follows:

Except as otherwise provided in NAC 639.205, an application for any certificate, license or permit issued by the Board is only valid for 1 year after the date it is received by the Board unless the Board extends its period of validity. An applicant who does not provide all information and make all appearances required by the Board within 1 year after submission of the application must submit a new application.

28B

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop July 15, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 639.070

A REGULATION relating to controlled substances; adding certain substances commonly classified as "designer benzodiazepines" to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

Section 1. NAC 453.510 is hereby amended to read as follows:

453.510 1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: Acryloylfentanyl);

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethadol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (some other trade names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (some other trade names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine)

Fentanyl Carbamate (Ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate);

4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) ~~(some trade or other names: Para-fluoroisobutyryl fentanyl);~~

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

~~3~~-Methylfentanyl ~~(N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);~~

~~3~~-Methylthiofentanyl ~~(N-[(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);~~

Methoxyacetyl fentanyl ~~(2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);~~

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);

Fluoroacryl fentanyl;

Fluoro furanyl fentanyl;

Methyl acetyl fentanyl);

Phenylpropanoyl fentanyl;

Fluorobutyryl fentanyl);

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl).

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

~~Para~~ fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyldihydrocodeine;

Acetylfentanyl;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazolo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

All 2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivatives thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N-o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-BOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe)

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy-N,N-dimethyltryptamine; 4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT)

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4-ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4h-

benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin-2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one**);**

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH 018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA)

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22)

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine *(some trade or other names: MMDA)*;

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-Dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48)

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (some trade or other names: ADB-CHMINCA or MAB-CHMINACA)

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: ADB-PINACA)

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: AB-FUBINACA)

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (some trade or other names: AB-CHMINACA)

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one**;** 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro-2H-1,4-benzodiazepin-2-one**;** 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1 ^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1- pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC)

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin-2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine**;** Pirazolam**);**

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; Tabernanthe iboga);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzo[f]isochromene-7-carboxylate);

Ethylamine analog of phencylidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phencyclohelyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidinde (some trade or other names: 1-1(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP)

➥ For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone

or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: Alpha-PHP);

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidine-1-yl)butan-1-one, alpha-pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha-pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha-aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,N-dimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4-methylenedioxycathinone; N,N-dimethyl-β-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA)

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA)

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4-FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1-one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)-2-(methylamino)propan-1-one, 2-FMC);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4’-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N-Methylcathinone, cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482); or

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α-methylaminovalerophenone)

Pentylone (some other trade names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K)

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule Tetrahydrocannabinols (natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as; Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers,

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as; Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers,

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule, and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or the resinous extractives of Cannabis sp. or synthetic substances. Derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous

extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,is not a controlled substance.

28C

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop July 15, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 639.070

A REGULATION relating to controlled substances; adding remimazolam to the controlled substances listed in Schedule IV; and providing other matters properly relating thereto.

Section 1. NAC 453.540 is hereby amended to read as follows:

NAC 453.540 Schedule IV.

1. Schedule IV consists of the drugs and other substances listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs, including, without limitation, their salts, calculated as the free anhydrous base of alkaloid, is hereby enumerated on schedule IV, in quantities:

(a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; or

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy-butane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alprazolam;
Barbital;
Bromazepam;
Butorphanol;
Camazepam;
Carisoprodol;
Chloral betaine;
Chloral hydrate;
Chlordiazepoxide;
Clobazam;
Clonazepam;
Clorazepate;

Clotiazepam;
Cloxazolam;
Delorazepam;
Diazepam;
Dichloralphenazone;
Eluxadoline;
Estazolam;
Ethchlorvynol;
Ethinamate;
Ethyl loflazepate;
Fludiazepam;
Flunitrazepam;
Flurazepam;
Halazepam;
Haloxazolam;
Ketazolam;
Lemborexant
Loprazolam;
Lorazepam;
Lorcaserin;
Lormetazepam;
Mebutamate;
Medazepam;
Meprobamate;
Methohexital;
Methylphenobarbital (mephobarbital);
Midazolam;
Nimetazepam;
Nitrazepam;
Nordiazepam;
Oxazepam;
Oxazolam;
Paraldehyde;
Petrichloral;
Phenobarbital;
Pinazepam;
Prazepam;
Quazepam;
***Remimazolam*;**
Suvorexant
Temazepam;
Tetrazepam;
Triazolam;
Zaleplon;
Zolpidem; or
Zopiclone.

4. Any material, compound, mixture or preparation which contains any quantity of fenfluramine, including, without limitation, its salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible, is hereby enumerated on schedule IV. For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV:

Cathine ((+)-norpseudoephedrine);
Diethylpropion;
Fencamfamin;
Fenproporex;
Mazindol;
Mefenorex;
Modafinil;
Pemoline (including organometallic complexes and chelates thereof);
Phentermine;
Pipradrol;
Sibutramine; or
SPA ((-)-dimethylamino-1,2,diphenylethane).

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including, without limitation, its salts, is hereby enumerated on schedule IV.

28D

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop – July 15, 2021

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~***omitted material***~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; SB190

A REGULATION relating to contraceptives; establishing a protocol under which a pharmacist may dispense self-administered hormonal contraceptives to any patient; authorizing a pharmacist to dispense self-administered hormonal contraceptives to any patient; and providing other matters properly relating thereto.

NAC Chapter 639 is hereby amended to add new sections to read as follows:

Self-Administered Hormonal Contraceptive Protocol for Pharmacists

1. ***A pharmacist dispensing a self-administered hormonal contraceptive must:***
   a) ***Complete a two (2) hour education course approved by Accreditation Council for Pharmacy Education (ACPE) or American College of Obstetricians and Gynecologists (ACOG) regarding self-administered contraceptives, including risk assessment, and contraindications. The certification must be maintained and readily retrievable during the time of dispensing, and for two (2) years after dispensing of self-administered hormonal contraceptive(s) has terminated;***
   b) ***Notify the Board of the Pharmacy that he/she intends to dispense self-administered hormonal contraceptives on a form provided by the Board; and***
   c) ***Follow the protocol in Section 2.***
2. ***If a patient requests a self-administered hormonal contraceptive pursuant to Section 1, then the pharmacist shall:***
   a) ***Have the patient complete a Risk Assessment Questionnaire (RAC) in Subsection 2(j);***
   b) ***Review the RAC responses with the patient;***
   c) ***Develop and utilize a treatment algorithm that takes into account training/education, risk assessment, and current United States Medical Eligibility Criteria (USMEC), including the Summary of the USMEC, as formulated by the Centers for Disease Control and Prevention (CDC), which must include, but not limited to:***
      1) ***Health and history screening;***
      2) ***Pregnancy screening;***
      3) ***Disease screening;***
      4) ***Medication screening;***
      5) ***Blood pressure screening;***
      6) ***Patient preference for treatment; and***
      7) ***Discussion of the treatment plan with the patient.***

d) If the determination made based upon the algorithm that it is unsafe to dispense, then the pharmacist must:
1) Not dispense the self-administered hormonal contraceptive;
2) Refer the patient to the patient's attending provider or qualified provider of health care;
3) Provide a copy of the completed RAC; and
4) Provide a copy of the written record of the requested contraceptive.
e) If the determination made based upon the algorithm that it is safe to dispense, then the pharmacist shall counsel the patient and provide information on the product dispensed, including, but not limited to:
1) Proper administration and storage of the dispensed contraceptive;
2) Dosage;
3) Effectiveness;
4) Potential side effects;
5) The need to use other methods of contraception, if appropriate;
6) The importance of obtaining recommended tests and screening from the patient's attending provider or another qualified provider of health care who specializes in women's health;
7) The effectiveness of long-acting, reversible contraceptives as an alternative to self-administered hormonal contraceptives;
8) When to seek emergency medical services as a result of administering a self-administered hormonal contraceptive; and
9) The risk of contracting a sexually transmitted infection (STI) and ways to reduce that risk.
f) If the pharmacist dispenses a self-administered contraceptive, then the pharmacist shall provide:
1) A copy of the completed RAC;
2) The written record of the requested contraceptive;
3) The written record of the contraceptive dispensed; and
4) The self-administered contraceptive in a container to which is affixed a label which clearly shows:
I. The date;
II. The name, address, and serial number as required in Section(2)(g)(2);
III. The number of dosage units;
IV. Specific directions for use;
V. The expiration date of the effectiveness of the contraceptive dispensed;
VI. The proprietary or generic name of the contraceptive; and
VII. The strength of the contraceptive.
g) The pharmacy shall maintain the following records for two (2) years:
1) A copy of the completed RAC; and
2) A written serialized numbered record of the self-administered hormonal contraceptive dispensed within the files of prescriptions.
h) If the pharmacist dispenses a self-administered contraceptive:
1) A twelve (12) months supply may be dispensed; or

2) *An initial supply may be dispensed with refills up to a twelve (12) months supply.*

i) *A pharmacist sharing a common electronic database that contains a copy of a patient's RAC may dispense a contraceptive pursuant to Subsection (h)(2) if the pharmacist reviews the RAC, discusses the RAC with the patient, answers questions, labels the contraceptive pursuant to Subsection (f)(4), and counsels pursuant to Subsection (e).*

j) *Risk Assessment Questionnaire form*

HORMONAL CONTRACEPTIVE RISK ASSESSMENT QUESTIONNAIRE FOR PATIENT COMPLETION

Note to patient: complete and print out this questionnaire and bring to your pharmacy for self-administered contraceptives. You should call your pharmacy first to make certain the pharmacy is able to provide this service. You may also obtain the questionnaire from participating pharmacies.

*Patient Name:*_____ *Date:*_____
Date of Birth: _____ *Age:*_____ *Weight:*_____ *Height:*_____
*Email address:*_____ *Telephone Number:*_____

☐ ☐

*What was the date of your last woman's health clinical visit?*_____/_____/_____
Any allergies to medications? Yes No
*If yes, list them here:*_____

☐ ☐ ☐ ☐

Do you have a preferred method of birth control that you would like to use?
A daily pill *A weekly patch* *A monthly vaginal ring* *Injectable (every 3 months)*

*Reviewing Pharmacist:*_____ *Date:*_____

1	*Do you think you could be pregnant now?*	*Yes* ☐	*No* ☐
2	*What was the first date of your last menstrual period?* _____/_____/_____		
3	*Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection?*	*Yes* ☐	*No* ☐
	- *Have you previously had contraceptives dispensed to you by a pharmacist?*	*Yes* ☐	*No* ☐
4	*Did you ever experience a bad reaction to using hormonal birth control?*	*Yes* ☐	*No* ☐
	- *If yes, what kind of reaction occurred?*		
5	*Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?*	*Yes* ☐	*No* ☐
6	*Have you ever been told by a medical professional not to take hormones?*	*Yes* ☐	*No* ☐
7	*Do you smoke cigarettes?*	*Yes* ☐	*No* ☐
8	*Have you had a recent change in vaginal bleeding that worries you?*	*Yes* ☐	*No* ☐
9	*Have you given birth within the past 21 days?*	*Yes* ☐	*No* ☐

	- *If yes, how long ago?*		
10	*Are you currently breastfeeding?*	*Yes* ☐	*No* ☐
11	*Do you have diabetes?*	*Yes* ☐	*No* ☐
12	*Do you get migraine headaches?*	*Yes* ☐	*No* ☐
	- *If yes, have you ever had headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?*	*Yes* ☐	*No* ☐
13	*Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)*	*Yes* ☐	*No* ☐
14	*Did you ever have a heart attack or stroke, or been told you have heart disease?*	*Yes* ☐	*No* ☐
15	*Have you ever had a blood clot?*	*Yes* ☐	*No* ☐
16	*Have you ever been told by a medical professional that you are at a high risk of developing a blood clot?*	*Yes* ☐	*No* ☐
17	*Did you have bariatric surgery or stomach reduction surgery?*	*Yes* ☐	*No* ☐
18	*Have you had recent major surgery or are you planning to have surgery in the next four (4) weeks?*	*Yes* ☐	*No* ☐
19	*Will you be immobile for a long period of time? (e.g. planning a long airplane trip, etc.)*	*Yes* ☐	*No* ☐
20	*Do you have or have you ever had breast cancer?*	*Yes* ☐	*No* ☐
21	*Do you have or have you ever had hepatitis, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?*	*Yes*	*No* ☐
22	*Do you have lupus, rheumatoid arthritis, or any blood disorders?*	*Yes* ☐	*No* ☐
23	*Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?*	*Yes* ☐	*No* ☐
	- *If yes, list the medications here:*		
24	*Do you have any other medical problems or take regular medication(s)?*	*Yes* ☐	*No* ☐
	- *If yes, list medications here:*		
25	*Do you take any herbal or vitamin supplements?*	*Yes* ☐	*No* ☐
	- *If yes, list supplements here:*		

*Patient Signature:*_____ *Date:*_____

1) Health and History Screen
Review Hormonal Contraceptive Risk Assessment Questionnaire for Patient Completion
To evaluate health and history, refer to USMEC.
No contraindications, then proceed to next step
Hormonal contraceptives contraindicated → Refer

Contraindicating Condition(s) → Refer

No Contraindicating Conditions

2) Pregnancy Screen
a. Did you have a baby less than six (6) months ago, are you fully or almost fully breast-feeding, *AND* have you had no menstrual period since the delivery?
b. Did you have a baby in the last four (4) weeks?
c. Did you have a miscarriage or abortion in the last seven (7) days?
d. Did your last menstrual period start within the past seven (7) days?
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out → Refer

Possible Pregnancy → Refer

Patient is not pregnant

3) Medication and Disease State Screen (Questionnaire #s 13, 19 + medication list)
Caution: Long-term corticosteroid therapy
*(*PLEASE ALWAYS REFER TO CURRENT MEC*)*

Contraindicating Diseases/ Medications → Refer

No Contraindicating Diseases/Medications

4) Blood Pressure Reading
Take and document patient's current blood pressure. Is BP <160/100?
Note: RPH may choose to take a second reading, if initial reading is high.

BP ≥ 160/100 → Refer

BP < 160/100

5) Discuss DMPA therapy with patient
a. Address any unexplained vaginal bleeding that worries patient (Questionnaire #8) – Refer when necessary, such as when not related to a recent pap or sexual intercourse.
b. Counseling – Discuss the management and expectations of side effects (bleeding irregularities, *etc.*)
c. Counseling – Discuss plans for follow-up visits, particularly for q 3 month administration of DMPA; stress importance of returning for next injection within 11-13 weeks of previous injection. Provide patient with specific calendar date range for next injection.
d. Counseling – Caution with use of DMPA > 2 years (due to loss of bone mineral density). For therapy > 2 years, consultation with healthcare professional is indicated.

First dose of DMPA

Q 3 month dose of DMPA

6) Dispense DMPA
Pharmacist shall dispense dep-medroxyprogesterone and administer the first does, monitor patient for 20 minutes for adverse reactions.

Note: Instruct patient that if this injection is not within seven (7) days of start of her period, then abstain or use backup method for seven (7) days.

6) Ongoing administration of DMPA

Pharmacist shall confirm that date of last injection was within 11-15 weeks.

If > 15 weeks ago, then pharmacist should rule out pregnancy (repeat step 2, and document), and instruct patient to abstain or use backup method for seven (7) days. Pharmacist will counsel patient on how to self-administer.

If between 11-15 weeks ago, administer the medication.

Do not administer if < 11 weeks ago

7) Discuss and Provide Referral/Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to care provider about contraception use

STANDARD PROCEDURES ALGORITHM FOR SELF-ADMINISTERED CONTRACEPTIVES (excluding DMPA)

1) Health and History Screen
Review Hormonal Contraceptive Risk Assessment Questionnaire for Patient Completion
To evaluate health and history, refer to USMEC.
No contraindications, then proceed to next step
Hormonal contraceptives contraindicated → Refer

Contraindicating Condition(s) → Refer

No Contraindicating Conditions

2) Pregnancy Screen
a. Did you have a baby less than six (6) months ago, are you fully or almost fully breast-feeding, AND have you had no menstrual period since the delivery?
b. Did you have a baby in the last four (4) weeks?
c. Did you have a miscarriage or abortion in the last seven (7) days?
d. Did your last menstrual period start within the past seven (7) days?
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
f. Have you been using a reliable contraceptive method consistently and correctly?

If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out → Refer

Possible Pregnancy → Refer

Patient is not pregnant

3) Medication Screen (Questionnaire #s 23, 24, and 25 + medication list) (Corticosteroids – refer to DMPA algorithm)
Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturates, herbs, and supplements, including:

carbamazepine	lumacaftor/ivacaftor	primidone (*PLEASE ALWAYS REFER TO CURRENT MEC*)
felbamate	oxcarbazepine	rifampin/rifabutin
griseofulvin	phenobarbital	topiramate
lamotrigine	phenytoin	fosamprenavir (when not combine with ritonavir)

Contraindicating Medications → Refer

No Contraindicating Medications

4) Blood Pressure Screen
Take and document patient's current blood pressure. Is BP <140/90?
Note: RPH may choose to take a second reading, if initial reading is high.

BP ≥ 140/90 → Refer or consider POP

BP < 140/90

5) Evaluate patient history, preference, and current therapy for selection of treatment

Patient NOT currently on birth control

5a) Choose Contraception
Initiate contraception based on patient preferences, adherence, and history for new therapy

Dispense up to twelve (12) months of desired contraception (quantity based on professional judgment and patient preference)

Patient is currently on birth control

5b) Choose Contraception
Continue current form of pills or patch, if no change is necessary
-or-
Alter therapy based on patient concerns, such as side effects patient may be experiencing; or refer, if appropriate

Dispense up to twelve (12) months of desired contraception (quantity based on professional judgment and patient preference)

6) Discuss Initiation Strategy for Initial Treatment/Change in Treatment (as applicable)
a. Counseling – Quick start – Instruct patient she may begin contraceptive today; use backup method for seven (7) days.
b. Counseling – Discuss the management and expectations of side effects (bleeding irregularities, *etc.*)
c. Counseling – Discuss adherence and expectations for follow-up visits to a provider of health care.

7) Discuss and Provide Referral/Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to attending provider or provider of health care about contraception use

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <20 yrs:2 ≥20 yrs:1		Menarche to <20 yrs:2 ≥20 yrs:1		Menarche to <18 yrs:1 18-45 yrs:1 >45 yrs:1		Menarche to <18 yrs:2 18-45 yrs:1 >45 yrs:2		Menarche to <18 yrs:1 18-45 yrs:1 >45 yrs:1		Menarche to <40 yrs:1 ≥40 yrs:2	
Anatomical abnormalities	a) Distorted uterine cavity	4		4									
	b) Other abnormalities	2		2									
Anemias	a) Thalassemia	2		1		1		1		1		1	
	b) Sickle cell disease‡	2		1		1		1		1		2	
	c) Iron-deficiency anemia	2		1		1		1		1		1	
Benign ovarian tumors	(*including cysts*)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	1		2		2*		2*		2*		2*	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer‡												
	i) Current	1		4		4		4		4		4	
	ii) Past and no evidence of current disease for 5 years	1		3		3		3		3		3	
Breastfeeding	a) <21 days postpartum					2*		2*		2*		4*	
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE					2*		2*		2*		3*	
	ii) Without other risk factors for VTE					2*		2*		2*		3*	
	c) 30-42 days postpartum												
	i) With other risk factors for VTE					1*		1*		1*		3*	
	ii) Without other risk factors for VTE					1*		1*		1*		2*	
	d) >42 days postpartum					1*		1*		1*		2*	
Cervical cancer	Awaiting treatment	4	2	4	2	2		2		1		2	
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		1		2		2		2		1		2	
Cirrhosis	a) Mild (*compensated*)	1		1		1		1		1		1	
	b) Severe‡ (*decompensated*)	1		3		3		3		3		4	
Cystic fibrosis‡		1*		1*		1*		2*		1*		1*	
Deep venous thrombosis (DVT)/Pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy												
	i) Higher risk for recurrent DVT/PE	1		2		2		2		2		4	
	ii) Lower risk for recurrent DVT/PE	1		2		2		2		2		3	
	b) Acute DVT/PE	2		2		2		2		2		4	
	c) DVT/PE and established anticoagulant therapy for at least 3 months												
	i) Higher risk for recurrent DVT/PE	2		2		2		2		2		4*	
	ii) Lower risk for recurrent DVT/PE	2		2		2		2		2		3*	
	d) Family history (*first-degree relatives*)	1		1		1		1		1		2	
	e) Major surgery												
	i) With prolonged immobilization	1		2		2		2		2		4	
	ii) Without prolonged immobilization	1		1		1		1		1		2	
	f) Minor surgery without immobilization	1		1		1		1		1		1	
Depressive disorders		1*		1*		1*		1*		1*		1*	

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Diabetes	a) History of gestational disease	1		1		1		1		1		1	
	b) Nonvascular disease												
	i) Non-insulin dependent	1		2		2		2		2		2	
	ii) Insulin dependent	1		2		2		2		2		2	
	c) Nephropathy/retinopathy/neuropathy‡	1		2		2		3		2		3/4*	
	d) Other vascular disease or diabetes of >20 years' duration‡	1		2		2		3		2		3/4*	
Dysmenorrhea	Severe	2		1		1		1		1		1	
Endometrial cancer‡		4	2	4	2	1		1		1		1	
Endometrial hyperplasia		1		1		1		1		1		1	
Endometriosis		2		1		1		1		1		1	
Epilepsy‡	(*see also Drug Interactions*)	1		1		1*		1*		1*		1*	
Gallbladder disease	a) Symptomatic												
	i) Treated by cholecystectomy	1		2		2		2		2		2	
	ii) Medically treated	1		2		2		2		2		3	
	iii) Current	1		2		2		2		2		3	
	b) Asymptomatic	1		2		2		2		2		2	
Gestational trophoblastic disease‡	a) Suspected GTD (immediate postevacuation)												
	i) Uterine size first trimester	1*		1*		1*		1*		1*		1*	
	ii) Uterine size second trimester	2*		2*		1*		1*		1*		1*	
	b) Confirmed GTD												
	i) Undetectable/non-pregnant ß-hCG levels	1*	1*	1*	1*	1*		1*		1*		1*	
	ii) Decreasing ß-hCG levels	2*	1*	2*	1*	1*		1*		1*		1*	
	iii) Persistently elevated ß-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2*	1*	2*	1*	1*		1*		1*		1*	
	iv) Persistently elevated ß-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4*	2*	4*	2*	1*		1*		1*		1*	
Headaches	a) Nonmigraine (mild or severe)	1		1		1		1		1		1*	
	b) Migraine												
	i) Without aura (includes menstrual migraine)	1		1		1		1		1		2*	
	ii) With aura	1		1		1		1		1		4*	
History of bariatric surgery‡	a) Restrictive procedures	1		1		1		1		1		1	
	b) Malabsorptive procedures	1		1		1		1		3		COCs: 3 P/R: 1	
History of cholestasis	a) Pregnancy related	1		1		1		1		1		2	
	b) Past COC related	1		2		2		2		2		3	
History of high blood pressure during pregnancy		1		1		1		1		1		2	
History of Pelvic surgery		1		1		1		1		1		1	
HIV	a) High risk for HIV	1*	1*	1*	1*	1		1		1		1	
	b) HIV infection					1*		1*		1*		1*	
	i) Clinically well receiving ARV therapy	1	1	1	1	If on treatment, see Drug Interactions							
	ii) Not clinically well or not receiving ARV therapy‡	2	1	2	1	If on treatment, see Drug Interactions							

Key:

1 No restriction (method can be used)	3 Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	4 Unacceptable health risk (method not to be used)

Abbreviations: ARV = antiretroviral, C=continuation of contraceptive method; CHC=combined hormonal contraception (pill, patch, and, ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring; SSRI=selective serotonin reuptake inhibitor; ‡ Condition that exposes a woman to increased risk as a result of pregnancy. *Please see the complete guidance for a clarification to this classification: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm.

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (*properly taken measurements*)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100‡	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Inflammatory bowel disease	(*Ulcerative colitis, Crohn's disease*)	1		1		1		2		2		2/3*	
Ischemic heart disease‡	Current and history of	1		2	3	2	3	3		2	3	4	
Known thrombogenic mutations‡		1*		2*		2*		2*		2*		4*	
Liver tumors	a) Benign												
	i) Focal nodular hyperplasia	1		2		2		2		2		2	
	ii) Hepatocellular adenoma‡	1		3		3		3		3		4	
	b) Malignant‡ (hepatoma)	1		3		3		3		3		4	
Malaria		1		1		1		1		1		1	
Multiple risk factors for atherosclerotic cardiovascular disease	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1		2		2*		3*		2*		3/4*	
Multiple sclerosis	a) With prolonged immobility	1		1		1		2		1		3	
	b) Without prolonged immobility	1		1		1		2		1		1	
Obesity	a) Body mass index (BMI) ≥30 kg/m²	1		1		1		1		1		2	
	b) Menarche to <18 years and BMI ≥ 30 kg/m²	1		1		1		2		1		2	
Ovarian cancer‡		1		1		1		1		1		1	
Parity	a) Nulliparous	2		2		1		1		1		1	
	b) Parous	1		1		1		1		1		1	
Past ectopic pregnancy		1		1		1		1		2		1	
Pelvic inflammatory disease	a) Past												
	i) With subsequent pregnancy	1	1	1	1	1		1		1		1	
	ii) Without subsequent pregnancy	2	2	2	2	1		1		1		1	
	b) Current	4	2*	4	2*	1		1		1		1	
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function												
	i) <6 months	2		2		1		1		1		4	
	ii) ≥6 months	2		2		1		1		1		3	
	b) Moderately or severely impaired cardiac function	2		2		2		2		2		4	
Postabortion	a) First trimester	1*		1*		1*		1*		1*		1*	
	b) Second trimester	2*		2*		1*		1*		1*		1*	
	c) Immediate postseptic abortion	4		4		1*		1*		1*		1*	
Postpartum (*nonbreastfeeding women*)	a) <21 days					1		1		1		4	
	b) 21 days to 42 days												
	i) With other risk factors for VTE					1		1		1		3*	
	ii) Without other risk factors for VTE					1		1		1		2	
	c) >42 days					1		1		1		1	
Postpartum (*in breastfeeding or non-breastfeeding women, including cesarean delivery*)	a) <10 minutes after delivery of the placenta												
	i) Breastfeeding	1*		2*									
	ii) Nonbreastfeeding	1*		1*									
	b) 10 minutes after delivery of the placenta to <4 weeks	2*		2*									
	c) ≥4 weeks	1*		1*									
	d) Postpartum sepsis	4		4									

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Pregnancy		4*		4*		NA*		NA*		NA*		NA*	
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	2	1	1		2/3*		1		2	
	b) Not on immunosuppressive therapy	1		1		1		2		1		2	
Schistosomiasis	a) Uncomplicated	1		1		1		1		1		1	
	b) Fibrosis of the liver‡	1		1		1		1		1		1	
Sexually transmitted diseases (STDs)	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	1		1		1		1	
	b) Vaginitis (*including trichomonas vaginalis and bacterial vaginosis*)	2	2	2	2	1		1		1		1	
	c) Other factors relating to STDs	2*	2	2*	2	1		1		1		1	
Smoking	a) Age <35	1		1		1		1		1		2	
	b) Age ≥35, <15 cigarettes/day	1		1		1		1		1		3	
	c) Age ≥35, ≥15 cigarettes/day	1		1		1		1		1		4	
Solid organ transplantation‡	a) Complicated	3	2	3	2	2		2		2		4	
	b) Uncomplicated	2		2		2		2		2		2*	
Stroke‡	History of cerebrovascular accident	1		2		2	3	3		2	3	4	
Superficial venous disorders	a) Varicose veins	1		1		1		1		1		1	
	b) Superficial venous thrombosis (acute or history)	1		1		1		1		1		3*	
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*		3*		3*	3*	3*		4*	
	b) Severe thrombocytopenia	3*	2*	2*		2*		3*	2*	2*		2*	
	c) Immunosuppressive therapy	2*	1*	2*		2*		2*	2*	2*		2*	
	d) None of the above	1*	1*	2*		2*		2*	2*	2*		2*	
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid	1		1		1		1		1		1	
Tuberculosis‡ (*see also Drug Interactions*)	a) Nonpelvic	1	1	1	1	1*		1*		1*		1*	
	b) Pelvic	4	3	4	3	1*		1*		1*		1*	
Unexplained vaginal bleeding	(suspicious for serious condition) before evaluation	4*	2*	4*	2*	3*		3*		2*		2*	
Uterine fibroids		2		2		1		1		1		1	
Valvular heart disease	a) Uncomplicated	1		1		1		1		1		2	
	b) Complicated‡	1		1		1		1		1		4	
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1		1	1	2		2		2		1	
	b) Heavy or prolonged bleeding	2*		1*	2*	2*		2*		2*		1*	
Viral hepatitis	a) Acute or flare	1		1		1		1		1		3/4*	2
	b) Carrier/Chronic	1		1		1		1		1		1	1
Drug Interactions													
Antiretrovirals used for prevention (PrEP) or treatment of HIV	Fosamprenavir (FPV) All other ARVs are 1 or 2 for all methods.	1/2*	1*	1/2*	1*	2*		2*		2*		3*	
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1		1		2*		1*		3*		3*	
	b) Lamotrigine	1		1		1		1		1		3*	
Antimicrobial therapy	a) Broad spectrum antibiotics	1		1		1		1		1		1	
	b) Antifungals	1		1		1		1		1		1	
	c) Antiparasitics	1		1		1		1		1		1	
	d) Rifampin or rifabutin therapy	1		1		2*		1*		3*		3*	
SSRIs		1		1		1		1		1		1	
St. John's wort		1		1		2		1		2		2	

Updated in 2020. This summary sheet only contains a subset of the recommendations from the U.S. MEC. For complete guidance, see: https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm. Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condomreduces the risk of STDs and HIV.

CS314239-A

Centers for Disease Control and Prevention

Recommendations and Reports / July 29, 2016 / 65(3);1–104

Please note: ***An update has been published for this report. To view the update, please click here.***

Kathryn M. Curtis, PhD[1]; Naomi K. Tepper, MD[1]; Tara C. Jatlaoui, MD[1]; Erin Berry-Bibee, MD[1,2]; Leah G. Horton, MSPH[1]; Lauren B. Zapata, PhD[1]; Katharine B. Simmons, MD[1,2]; H. Pamela Pagano, MPH[1]; Denise J. Jamieson, MD[1]; Maura K. Whiteman, PhD[1]
(View author affiliations)

View suggested citation

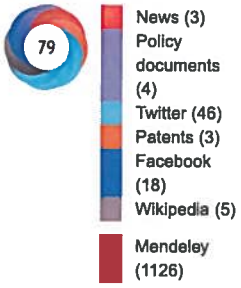
Summary

The 2016 U.S. Medical Eligibility Criteria for Contraceptive Use *(U.S. MEC) comprises recommendations for the use of specific contraceptive methods by women and men who have certain characteristics or medical conditions. These recommendations for health care providers were updated by CDC after review of the scientific evidence and consultation with national experts who met in Atlanta, Georgia, during August 26–28, 2015. The information in this report updates the 2010 U.S. MEC* (CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010:59 [No. RR-4]). *Notable updates include the addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort; revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate; and revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases, and human immunodeficiency virus; and women who are receiving antiretroviral therapy. The recommendations in this report are intended to assist health care providers when they counsel women, men, and couples about contraceptive method choice. Although these recommendations are meant to serve as a source of clinical guidance, health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients. Persons should seek advice from their health care providers when considering family planning options.*

Top

Article Metrics

Altmetric:



Citations: 429

Views: 124,762

Views equals page views plus PDF downloads

Metric Details

Boxes

Box 1

Box 2

Related Materials

PDF [1M]

Introduction

Approximately 45% of all pregnancies that occur in the United States are unintended (*1*), with associated increased risks for adverse maternal and infant health outcomes (*2*) and increased health care costs (*3*). Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including long-acting reversible contraception methods such as intrauterine devices (IUDs) and implants, to reduce the risk for an unintended pregnancy. However, with these expanded options comes the need for evidence-based guidance to help health care providers offer quality family planning care to their patients, including choosing the most appropriate contraceptive method for individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness.

In 2010, CDC published the first *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC), which provided recommendations on safe use of contraceptive methods for women with various medical conditions and other characteristics (and was adapted from global guidance developed by the World Health Organization [WHO MEC]) (*4,5*). U.S. MEC is a companion document to the *U.S. Selected Practice Recommendations for Contraceptive Use* (U.S. SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate (*6*). WHO intended for the global guidance to be used by local or national policy makers, family planning program managers, and the scientific community as a reference when they develop family planning guidance at the country or program level. During

2008–2010, CDC participated in a formal process to adapt the global guidance for appropriateness for use in the United States, which included rigorous identification and critical appraisal of the scientific evidence through systematic reviews, and input from national experts on how to translate that evidence into recommendations for U.S. health care providers (*5*). At that time, CDC committed to keeping this guidance up to date and based on the best available evidence, with full review every few years (*5*).

This document updates CDC's U.S. MEC 2010 (*5*), based on new evidence and input from experts. A summary of changes from U.S. MEC 2010 is provided (Appendix A). Notable updates include the following:

- addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort
- revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate
- revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases (STDs), and human immunodeficiency virus (HIV); and women who are receiving antiretroviral therapy

The goal of these recommendations is to remove unnecessary medical barriers to accessing and using contraception, thereby decreasing the number of unintended pregnancies. These recommendations are meant to serve as a source of clinical guidance for health care providers; health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients, who should seek advice from their health care providers when considering family planning options.

Top

Methods

Since publication of U.S. MEC 2010, CDC has monitored the literature for new evidence relevant to the recommendations through the WHO/CDC continuous identification of research evidence (CIRE) system. This system identifies new evidence as it is published and allows WHO and CDC to update systematic reviews and facilitate updates to recommendations as new evidence warrants. Automated searches are run in PubMed weekly, and the results are reviewed. Abstracts that meet specific criteria are added to the web-based CIRE system, which facilitates coordination and peer review of systematic reviews for both WHO and CDC (*7*). In 2014, CDC reviewed all of the existing recommendations in U.S. MEC 2010 for new evidence identified by CIRE that had the potential to lead to a changed recommendation. During August 27–28, 2014, CDC held a meeting in Atlanta, Georgia, of 11 family planning experts and representatives from partner organizations to solicit their input on the scope of and process for updating both U.S. MEC 2010 and U.S. SPR 2013. The participants were experts in family planning and represented various types of health care providers, as well as health care provider organizations. A list of participants is provided at the end of this report. Meeting participants discussed topics to be addressed in the update of U.S. MEC based on new evidence published since 2010 (identified through the CIRE system), topics addressed at a 2014 WHO meeting to update global guidance, and suggestions CDC received from health care providers for the addition of recommendations for women with medical conditions not yet included in U.S. MEC (e.g., from provider feedback through e-mail, public inquiry, and questions received at conferences). CDC identified several topics to consider when updating the guidance, including revision of existing recommendations for certain medical conditions or characteristics (breastfeeding, postpartum, HIV, receiving antiretroviral therapy, obesity, dyslipidemia, increased risk for STDs, superficial venous thrombosis, gestational trophoblastic disease, and migraine headaches), addition of recommendations for new medical conditions (cystic fibrosis, multiple sclerosis, use of certain psychotropic drugs, and St. John's wort), and addition of recommendations for new contraceptive methods (ulipristal acetate for emergency contraception). CDC determined that all other recommendations in U.S. MEC 2010 were up to date and consistent with the existing body of evidence for that recommendation.

In preparation for a subsequent expert meeting held during August 26–28, 2015, to review the scientific evidence for potential recommendations, CDC staff members and other invited authors listed at the end of this report conducted independent systematic reviews for each of the topics being considered. The purpose of these systematic reviews was to identify direct evidence about the safety of contraceptive method use by women with selected conditions (e.g., risk for disease progression or other adverse health effects in women with multiple sclerosis who use combined hormonal contraceptives [CHCs]). Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews (*8*,*9*), and strength and quality of the evidence were assigned using the system of the U.S. Preventive Services Task Force (*10*). When direct evidence was limited or not available, indirect evidence (e.g., evidence on surrogate outcomes or among healthy women) and theoretical issues were considered and either added to direct evidence within a systematic review or separately compiled for presentation to the meeting participants. Completed systematic reviews were peer reviewed by two or three experts and then provided to participants before the expert meeting. Reviews are referenced

and cited throughout this document; the full reviews appear in the published literature and contain the details of each review, including the systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessments. CDC staff continued to monitor new evidence identified through the CIRE system during the preparation for the August 2015 meeting.

During August 26–28, 2015, in Atlanta, Georgia, CDC held a meeting with 44 participants who were invited to provide their individual perspectives on the scientific evidence presented and potential recommendations. Twenty-nine of the participants represented a wide range of expertise in family planning provision and research, and included obstetricians/gynecologists, pediatricians, family physicians, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management; these individuals participated in the entire meeting. Fifteen participants with expertise relevant to specific topics on the meeting agenda provided information and participated in the discussion (e.g., an expert in cystic fibrosis was asked to provide general information about the condition and to assist in interpreting the evidence and any theoretical concerns on the use of contraceptive methods in women with the condition); these participants provided input only during the session for which their topics were discussed. Lists of participants and any potential conflicts of interest are provided at the end of this report. During the meeting, the evidence from the systematic review for each topic was presented, including direct evidence and any indirect evidence or theoretical concerns. Participants provided their perspectives on using the evidence to develop recommendations that would meet the needs of U.S. health care providers. After the meeting, CDC determined the recommendations in this report, taking into consideration the perspectives provided by the meeting participants. Feedback also was received from three external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These reviewers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. Areas of research that need additional investigation also were considered during the meeting (*11*).

Top

How to Use This Document

These recommendations are intended to help health care providers determine the safe use of contraceptive methods among women and men with various characteristics and medical conditions. Providers also can use the information in these recommendations when consulting with women, men, and couples about their selection of contraceptive methods. The tables in this document include recommendations for the use of contraceptive methods by women and men with particular characteristics or medical conditions. Each condition is defined as representing either an individual's characteristics (e.g., age or history of pregnancy) or a known preexisting medical or pathologic condition (e.g., diabetes or hypertension). The recommendations refer to contraceptive methods being used for contraceptive purposes; the recommendations do not consider the use of contraceptive methods for treatment of medical conditions because the eligibility criteria in these situations might differ. The conditions affecting eligibility for the use of each contraceptive method are classified into one of four categories (Box 1).

Using the Categories in Practice

Health care providers can use the eligibility categories when assessing the safety of contraceptive method use for women and men with specific medical conditions or characteristics. Category 1 comprises conditions for which no restrictions exist for use of the contraceptive method. Classification of a method/condition as category 2 indicates the method generally can be used, although careful follow-up might be required. For a method/condition classified as category 3, use of that method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be considered, and careful follow-up is required. Hence, provision of a contraceptive method to a woman with a condition classified as category 3 requires careful clinical judgement and access to clinical services. Category 4 comprises conditions that represent an unacceptable health risk if the method is used. For example, a smoker aged <35 years generally can use combined oral contraceptives (COCs) (category 2). However, for a woman aged ≥35 years who smokes <15 cigarettes per day, the use of COCs usually is not recommended unless other methods are not available or acceptable to her (category 3). A woman aged ≥35 years who smokes ≥15 cigarettes per day should not use COCs because of unacceptable health risks, primarily the risk for myocardial infarction and stroke (category 4). The programmatic implications of these categories might depend on the circumstances of particular professional or service organizations. For example, in some settings, a category 3 might mean that a special consultation is warranted.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a medical condition develops or worsens during use of a contraceptive method. When the categories differ for initiation and continuation, these differences are noted in the Initiation and Continuation columns. When initiation and continuation are not indicated, the category is the same for initiation and continuation of use.

On the basis of this classification system, the eligibility criteria for initiating and continuing use of a specific contraceptive method are presented in tables (Appendices A–K). In these tables, the first column indicates the condition. Several conditions are divided into subconditions to differentiate between varying types or severity of the condition. The second column classifies the condition for initiation or continuation (or both) into category 1, 2, 3, or 4. For certain conditions, the numeric classification does not adequately capture the recommendation; in these cases, the third column clarifies the numeric category. These clarifications were determined during the discussions of the scientific evidence and are considered a necessary element of the recommendation. The third column also summarizes the evidence for the recommendation if evidence exists. The recommendations for which no evidence is cited are based on expert opinion from either the WHO or U.S. expert meeting in which these recommendations were developed, and might be based on evidence from sources other than systematic reviews. For certain recommendations, additional comments appear in the third column and generally come from the WHO meeting or the U.S. meeting.

Recommendations for Use of Contraceptive Methods

The classifications for whether women with certain medical conditions or characteristics can use specific contraceptive methods are provided for intrauterine contraception, including the copper-containing IUD and levonorgestrel-releasing IUDs (Appendix B); progestin-only contraceptives (POCs), including etonogestrel implants, depot medroxyprogesterone acetate injections, and progestin-only pills (Appendix C); CHCs, including low-dose (containing ≤35 μg ethinyl estradiol) COCs, combined hormonal patch, and combined vaginal ring (Appendix D); barrier contraceptive methods, including male and female condoms, spermicides, diaphragm with spermicide, and cervical cap (Appendix E); fertility awareness–based methods (Appendix F); lactational amenorrhea method (Appendix G); coitus interruptus (Appendix H); female and male sterilization (Appendix I); and emergency contraception, including emergency use of the copper-containing IUD and emergency contraceptive pills (Appendix J). A table at the end of this report summarizes the classifications for the hormonal and intrauterine methods (Appendix K).

Contraceptive Method Choice

Many elements need to be considered by women, men, or couples at any given point in their lifetimes when choosing the most appropriate contraceptive method. These elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability. The guidance in this report focuses primarily on the safety of a given contraceptive method for a person with a particular characteristic or medical condition. Therefore, the classification of category 1 means that the method can be used in that circumstance with no restrictions with regard to safety but does not necessarily imply that the method is the best choice for that person; other factors, such as effectiveness, availability, and acceptability, might play an important role in determining the most appropriate choice. Voluntary informed choice of contraceptive methods is an essential guiding principle, and contraceptive counseling, when applicable, might be an important contributor to the successful use of contraceptive methods.

In choosing a method of contraception, dual protection from the simultaneous risk for HIV and other STDs also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs, including HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonococcal infection, and trichomoniasis (*12*). Although evidence is limited, use of female condoms can provide protection from acquisition and transmission of STDs (*12*). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (*12*). Additional information about prevention and treatment of STDs is available from the CDC *Sexually Transmitted Diseases Treatment Guidelines* (http://www.cdc.gov/std/treatment) (*12*).

Contraceptive Method Effectiveness

Contraceptive method effectiveness is critical for minimizing the risk for an unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (Figure). Methods that depend on consistent and correct use have a wide range of effectiveness. IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method.

Unintended Pregnancy and Increased Health Risk

For women with conditions that might make pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods might be the best choice to avoid unintended pregnancy (Figure). Women with these conditions should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure (Figure). Conditions included in U.S. MEC that are associated with increased risk for adverse health events as a result of pregnancy are identified throughout the document (Box 2). Some of the medical conditions included in U.S. MEC recommendations are treated with teratogenic drugs. While the woman's medical condition may not affect her eligibility to use certain contraceptive methods, women using teratogenic drugs are at increased risk for poor pregnancy outcomes; long-acting, highly effective contraceptive methods might be the best option to avoid unintended pregnancy or delay pregnancy until teratogenic drugs are no longer needed.

Top

Keeping Guidance Up to Date

Updating the evidence-based recommendations as new scientific evidence becomes available is a challenge. CDC will continue to work with WHO to identify and assess new relevant evidence as it becomes available and to determine whether changes in the recommendations are warranted (*7*). In most cases, U.S. MEC follows the WHO guidance updates, which typically occur every 5 years (or sooner if warranted by new data). However, CDC will review all WHO updates for their application in the United States. CDC also will identify and assess any new literature for the recommendations and medical conditions that are not included in the WHO guidance. CDC will completely review U.S. MEC every 5 years as well. Updates to the guidance will appear on the CDC U.S. MEC website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm).

Top

Acknowledgments

This report is based, in part, on the work of the Promoting Family Planning Team, Department of Reproductive Health and Research, World Health Organization, and its development of Medical Eligibility Criteria for Contraceptive Use, 5th edition.

U.S. Medical Eligibility Criteria for Contraceptive Use Participants

CDC Guideline Development Group for U.S. Medical Eligibility Criteria for Contraceptive Use and U.S. Selected Practice Recommendations for Contraceptive Use

Kathryn M. Curtis, PhD (Chair), Erin Berry-Bibee, MD, Suzanne G. Folger, PhD, Leah G. Horton, MSPH, Denise J. Jamieson, MD, Tara C. Jatlaoui, MD, Polly A. Marchbanks, PhD, H. Pamela Pagano, MPH, Halley E.M. Riley, MPH, Mirelys Rodriguez, Katharine B. Simmons, MD, Naomi K. Tepper, MD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia.

Invited Meeting Participants, August 27–28, 2014, Atlanta, Georgia

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Gale Burstein, MD, Erie County Department of Health, Buffalo, New York; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, Washington; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360 and American College of Obstetricians and Gynecologists, Durham, North Carolina; Deborah Nucatola, MD, Planned Parenthood Federation of America, New York, New York; Michael Policar, MD, University of California, San Francisco, California; Carolyn Westhoff, MD, Columbia University, New York, New York.

Systematic Review Presenters and Authors, Meeting, August 26–28, 2015, Atlanta, Georgia

Erin Berry-Bibee, MD, Kathryn M. Curtis, PhD, Leah G. Horton, MSPH, Denise J. Jamieson, MD, Tara C. Jatlaoui, MD, Polly A. Marchbanks PhD, Titilope Oduyebo, MD, Pamela Pagano, MPH, Halley E.M. Riley, MPH, Katharine B. Simmons, MD, Naomi K. Tepper, MD, Maura K. Whiteman, PhD, Lauren B. Zapata, PhD, CDC, Atlanta, Georgia; Monica Dragoman, MD, Mary E. Gaffield, PhD, Sharon J. Phillips, MD, Marleen Temmerman, MD, World Health Organization, Geneva, Switzerland; Andra James, MD, Duke University Medical Center, Durham, North Carolina; Nathalie Kapp, MD, HRA Pharma, Paris, France; Kavita Nanda, MD, FHI360, Durham, North Carolina; Seth Walker, MD, Emory University, Atlanta, Georgia.

Invited Meeting Participants, August 26–28, 2015, Atlanta, Georgia

Herbert Peterson, MD, University of North Carolina, Chapel Hill, North Carolina (Chair); Rebecca Allen, MD, American Society for Reproductive Medicine and Women and Infants Hospital, Providence, Rhode Island; Jean Anderson, MD, Johns Hopkins University, Baltimore, Maryland; Abbey Berenson, MD, University of Texas Medical Branch, Galveston, Texas; Amanda Black, MD, University of Ottawa, Ontario, Canada; Cora Collette Breuner, MD, American Academy of Pediatrics and Seattle Children's Hospital, Seattle, Washington; Gale Burstein MD, Erie County Department of Health, Buffalo, New York; Anne Calhoun, MD, University of North Carolina, Chapel Hill, North Carolina; Nahida Chakhtoura, MD, National Institutes of Health, Rockville, Maryland; Alicia Christy, MD, National Institutes of Health, Rockville, Maryland; Mitchell D. Creinin, MD, University of California, Davis, California; Linda Dominguez, Southwest Women's Health, Albuquerque, New Mexico; Alison Edelman, MD, Oregon Health and Science University, Portland, Oregon; Eve Espey, MD, University of New Mexico, Albuquerque, New Mexico; Emily Godfrey, MD, University of Washington, Seattle, Washington; Marji Gold, MD, Albert Einstein College of Medicine, Bronx, New York; Donald Goldstein, MD, Harvard Medical School, Boston, Massachusetts; Robert Hatcher, MD, Emory University, Atlanta, Georgia; Mark Hathaway, MD, JHPIEGO and Unity Healthcare, Washington, DC; Stephen Heartwell, MD, Susan Thompson Buffett Foundation, Omaha, Nebraska; Paula Hillard, MD, Stanford University, Palo Alto, California; Maria Houtchens, MD, Harvard Medical School, Boston, Massachusetts; Andra James, MD, Duke University Medical Center, Durham, North Carolina; Andrew Kaunitz, MD, University of Florida, Jacksonville, Florida; Myong-Jin Kim, Pharm-D, Food and Drug Administration, Rockville, Maryland; Barbara Konkle, MD, Bloodworks Northwest, Seattle, Washington; Tobias Kurth, MD, INSERM, Bordeaux, France; Miriam Labbok, MD, Academy of Breastfeeding Medicine and University of North Carolina, Chapel Hill, North Carolina; Reagan McDonald-Mosley, MD, Planned Parenthood Federation of America, New York, New York; Joan Meek, MD, American Academy of Pediatrics and Florida State University College of Medicine, Orlando, Florida; Mark Mirochnick, MD, Boston University, Boston, Massachusetts; Susan Moskosky, MS, U.S. Department of Health and Human Services, Rockville, Maryland; Kavita Nanda, MD, FHI360, Durham, North Carolina; Jeffrey Peipert, MD, Washington University, St. Louis, Missouri; Michael Policar, MD, University of California, San Francisco, California; Sarah Prager, MD, University of Washington, Seattle Washington; David Soper, MD, Medical University of South Carolina, Charleston, South Carolina; Lisa Soule, MD, Food and Drug Administration, Rockville, Maryland; Alison Stuebe, MD, American College of Obstetricians and Gynecologist and University of North Carolina, Chapel Hill, North Carolina; James Trussell, PhD, Princeton University, Princeton, New Jersey; Seth Walker, MD, Emory University, Atlanta, Georgia; Nanette Wenger, MD, Emory University, Atlanta, Georgia; Carolyn Westhoff, MD, Columbia University, New York, New York; Christopher Zahn, MD, American College of Obstetricians and Gynecologists, Washington, DC.

CDC Attendees

Wanda D. Barfield, MD, Peter Briss, MD, W. Craig Hooper, PhD, Jill Huppert, MD, Caroline King, PhD, Michele Mandel, Titilope Oduyebo, MD, Cria Perrine, MD, Sam Posner, PhD.

External Reviewers

Abigail R.A. Aiken, PhD, Princeton University, Princeton, New Jersey; Linda Burdette, PA-C, Premier Women's Health of Yakima, Yakima, Washington; Mimi Zieman, MD, Planned Parenthood Southeast, Atlanta, Georgia.

Conflicts of Interest for Invited Meeting Participants, August 26–28, 2015, Atlanta, Georgia

Rebecca Allen, Nexplanon trainer for Merck and Liletta trainer for Actavis, consultant, advisory board and education grant from Bayer; Mitchell D. Creinin, Nexplanon trainer for Merck, litigation consultant for Bayer, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Lemonaid – PolkaDoc app, research support to University of California, Davis from Medicines360, Contramed, Merck, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and Society of Family Planning; Linda Dominguez, speaker for Bayer, Merck, and Actavis; Alison Edelman, royalties from Up to Date, Inc., consultant for Genzyme, grant support from the National Institutes of Health and the Gates Foundation, travel funds from the World Health Organization, grant support and honorarium from Society of Family Planning, honorarium and travel funds from Contemporary Forum, trainer for Merck, consultant for Gynuity Health Projects, honorarium from CDC, Projects In Knowledge, and American Congress of Obstetricians and Gynecologists, advisory board for Agile Therapeutics; Eve Espey, travel funds from the American Congress of Obstetricians and Gynecologists, Society for Family Planning, and U.S. Food and Drug Administration, Reproductive and Drug Advisory Committee for U.S. Food and Drug Administration, travel funds and honoraria from Wayne State University, Telluride Conference, New Mexico Department of Health Clinician Conference, Planned Parenthood National Medical Conference and Society of Family Planning, British Columbia Contraception Access Research Team Conference, and American Congress of Obstetricians and Gynecologists annual meeting; Emily Godfrey, research funding from Bayer Women's Health, Prima-Temp, and Teva Pharmaceutical Industries, Ltd., trainer for Merck and Upstream USA, grant reviewer for Fellowship of Family Planning and Society of Family Planning Research Fund; Mark Hathaway, Liletta trainer and speaker for Actavis and Medicines360, Nexplanon trainer for Merck, advisory board for Contramed and Afaxys Pharmaceuticals; Paula Hillard, consultant for American Civil Liberties

Union, Advanced Health Media, CMEology, National Sleep Foundation, and Planned Parenthood Federation of America, honoraria from National Sleep Foundation, Dignity Health, CMEology, Advance Health Media, and Medscape, editorial board for Advanstar–Contemporary OB/GYN, board examiner for the American Board of Obstetrics and Gynecology, contract reviewer for the U.S. Department of Health and Human Services, editorial board for EBSCO–PEMSoft, Nexplanon trainer for Merck, scientific advisor to Proctor and Gamble, publication royalties from Wiley Blackwell Publishing; Andrew Kaunitz, advisory board participant of Allergan, Bayer, Merck, and Pfizer, clinical trial funding to University of Florida from Agile Therapeutics, Bayer, Merck; Mark Mirochnick, data and safety monitoring board for Merck and ViiV Healthcare, advisory board for Merck; Jeffrey Peipert, research funding from Bayer and Teva Pharmaceutical Industries, Ltd., advisory board for Perrigo; Michael Policar, litigation consultant for Bayer; James Trussell, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Bayer; Nanette Wenger, research grants from Alnylam Pharmaceuticals, Gilead Sciences, National Heart, Lung, and Blood Institute, Pfizer, and Society for Women's Health Research, consultant for Amgen, AstraZeneca, Gilead Sciences and Merck; Carolyn Westhoff, data and safety monitoring board for Merck and Bayer, advisory board for Agile Therapeutics, MicroChips Biotech, and Actavis, research support to Columbia University from Medicines360, León Farma, and ContraMed.

Handling Conflicts of Interest

To promote transparency, all participants were asked to disclose any potential conflicts of interest to CDC prior to the expert meeting and to report any potential conflicts of interest during the introductory portion of the expert meeting. All potential conflicts of interest are listed above. No participants were excluded from discussion based on potential conflicts of interest. CDC staff who ultimately decided and developed these recommendations have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters relevant to these recommendations.

Top

Corresponding author: Kathryn M. Curtis, PhD, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC. Telephone: 770-488-5200; E-mail: kmc6@cdc.gov.

Top

---

[1]Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC, Atlanta, Georgia; [2]Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, North Carolina

Top

Disclosure of Relationship CDC, our planners, and our content experts wish to disclose they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Planners have reviewed content to ensure there is no bias. This document will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception that some of the recommendations in this document might be inconsistent with package labeling.

Top

References

1. Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008–2011. N Engl J Med 2016;374:843–52. CrossRef PubMed
2. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. Stud Fam Plann 2008;39:18–38. CrossRef PubMed
3. Sonfield A, Kost K. Public costs from unintended pregnancies and the role of public insurance programs in paying for pregnancy-related care: national and state estimates for 2010. New York: Guttmacher Institute; 2015.
4. World Health Organization. Medical eligibility criteria for contraceptive use. 4th ed. Geneva, Switzerland: World Health Organization; 2009.
5. CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR Recomm Rep 2010;59(No. RR-4). PubMed
6. Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65(No. RR-4) .
7. Mohllajee AP, Curtis KM, Flanagan RG, Rinehart W, Gaffield ML, Peterson HB. Keeping up with evidence a new system for WHO's evidence-based family planning guidance. Am J Prev Med 2005;28:483–90. CrossRef PubMed
8. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. J Clin Epidemiol 2009;62:e1–34. CrossRef PubMed

PubMed

9. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Int J Surg 2010;8:336–41. CrossRef PubMed
10. Harris RP, Helfand M, Woolf SH, et al. Methods Work Group, Third US Preventive Services Task Force. Current methods of the US Preventive Services Task Force: a review of the process. Am J Prev Med 2001;20(Suppl):21–35. CrossRef PubMed
11. Horton L, Folger SG, Berry-Bibee E, Jatlaoui TC, Tepper NK, Curtis KM. Research gaps from evidence-based contraception guidance: the U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, and the U.S. Selected Practice Recommendations for Contraceptive Use, 2016. Contraception. In press 2016.
12. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-3). PubMed

Top

Abbreviations and Acronyms

Top

ARV = antiretroviral [therapy]
BMD = bone mineral density
BMI = body mass index
CHC = combined hormonal contraceptive
COC = combined oral contraceptive
Cu-IUD = copper-containing intrauterine device
DMPA = depot medroxyprogesterone acetate
DVT = deep venous thrombosis
ECP = emergency contraceptive pills
FAB = fertility awareness–based [methods]
hCG = human chorionic gonadotropin
HDL = high-density lipoprotein
HIV = human immunodeficiency virus
IBD = inflammatory bowel disease
IUD = intrauterine device
LARC = long-acting reversible contraception
LDL = low-density lipoprotein
LNG = levonorgestrel
LNG-IUD = levonorgestrel-releasing intrauterine device
NET-EN = norethisterone enantate
NNRTI = nonnucleoside reverse transcriptase inhibitor
NRTI = nucleoside reverse transcriptase inhibitor
PE = pulmonary embolism
PID = pelvic inflammatory disease
POC = progestin-only contraceptive
POP = progestin-only pill
SLE = systemic lupus erythematosus
SSRI = selective serotonin reuptake inhibitors
STD = sexually transmitted disease
UPA = ulipristal acetate
U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*
U.S. SPR = *U.S. Selected Practice Recommendations for Contraceptive Use*
VTE = venous thromboembolism

Top

BOX 1. Categories of medical eligibility criteria for contraceptive use

Return

1 = A condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

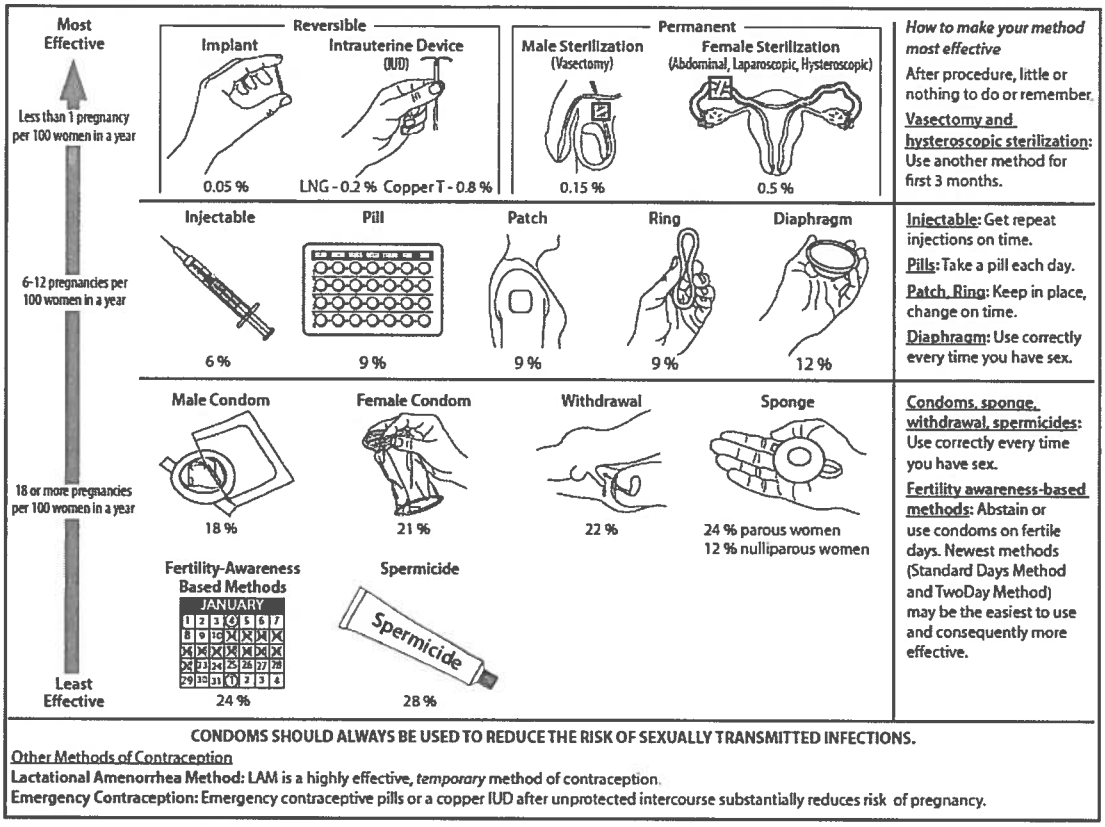
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

Top

FIGURE. Effectiveness of family planning methods*

Return



Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

Top

BOX 2. Conditions associated with increased risk for adverse health events as a result of pregnancy*

Return

Breast cancer

Complicated valvular heart disease

Cystic fibrosis

Diabetes: insulin dependent; with nephropathy, retinopathy, or neuropathy or other vascular disease; or of >20 years' duration

Endometrial or ovarian cancer

Epilepsy

Hypertension (systolic ≥160 mm Hg or diastolic ≥100 mm Hg)

History of bariatric surgery within the past 2 years

HIV: not clinically well or not receiving antiretroviral therapy

Ischemic heart disease

Gestational trophoblastic disease

Hepatocellular adenoma and malignant liver tumors (hepatoma)

Peripartum cardiomyopathy

Schistosomiasis with fibrosis of the liver

Severe (decompensated) cirrhosis

Sickle cell disease

Solid organ transplantation within the past 2 years

Stroke

Systemic lupus erythematosus

Thrombogenic mutations

Tuberculosis

*Long-acting, highly effective contraceptive methods might be the best choice for women with conditions that are associated with increased risk for adverse health events as a result of pregnancy. These women should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure.

Top

View Appendices

Top

Suggested citation for this article: Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR Recomm Rep 2016;65(No. RR-3):1–104. DOI: http://dx.doi.org/10.15585/mmwr.rr6503a1 .

MMWR and *Morbidity and Mortality Weekly Report* are service marks of the U.S. Department of Health and Human Services.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

References to non-CDC sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of pages found at these sites. URL addresses listed in *MMWR* were current as of the date of publication.

All HTML versions of *MMWR* articles are generated from final proofs through an automated process. This conversion might result in character translation or format errors in the HTML version. Users are referred to the electronic PDF version (https://www.cdc.gov/mmwr) and/or the original *MMWR* paper copy for printable versions of official text, figures, and tables.

Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov.

Page last reviewed: September 21, 2017

28E

Centers for Disease Control and Prevention

Pre-Exposure Prophylaxis (PrEP)

To get a PDF version of the information below and access other print resources for your practice and patients, visit our PrEP/PEP materials page.

What is PrEP?

PrEP is short for pre-exposure prophylaxis. It is the use of antiretroviral medication to prevent acquisition of HIV infection. PrEP is used by people without HIV who are at risk of being exposed to HIV through sexual contact or injection drug use. Two medications have been approved for use as PrEP by the FDA. Each consists of two drugs combined in a single oral tablet taken daily:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF – brand name **Truvada®**)
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF – brand name **Descovy®**)

These medications are approved to prevent HIV infection in adults and adolescents weighing at least 35 kg (77 lb) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV infection among all persons at risk through sex or injection drug use.
- Daily oral PrEP with F/TAF is recommended to prevent HIV infection among persons at risk through sex, excluding ***people at risk through receptive vaginal sex***. F/TAF has not yet been studied for HIV prevention for receptive vaginal sex.

PrEP should be considered part of a comprehensive prevention plan that includes a discussion about adherence to PrEP, condom use, other sexually transmitted infections (STIs), and other risk reduction methods.

What are the guidelines for prescribing PrEP?

Comprehensive guidelines for prescribing PrEP have been published by the Centers for Disease Control and Prevention (CDC) in *A Clinical Practice Guideline*,[1] including a *Clinical Providers' Supplement*.[2]

The Clinical Providers' Supplement contains additional tools for clinicians providing PrEP, such as a patient/provider checklist, patient information sheets, provider information sheets, a risk incidence assessment, supplemental counseling information, billing codes, and practice quality measures. If questions arise or if prescribing advice is needed, clinicians should consult the **National Clinicians Consultation Center PrEP Line @ 1-855-448-7737** (9:00 AM – 8:00 PM EST).

The U.S. Preventive Services Task Force has given PrEP a **grade A recommendation**.[3] This grade indicates that their review found that there is high certainty that the net benefit of this service is substantial. For more information, view the full recommendation rationale at **www.uspreventiveservicestaskforce.org** .

Who can prescribe PrEP?

Any licensed prescriber can prescribe PrEP. Specialization in infectious diseases or HIV medicine is not required. In fact, primary care providers who routinely see people at risk for HIV acquisition should consider offering PrEP to all eligible patients.[4]

To whom should I offer PrEP?

PrEP is for people without HIV who are at risk of acquisition from sex or injection drug use. People at risk who should be assessed for PrEP include:

- Sexually active gay and bisexual men without HIV
- Sexually active heterosexual men and women without HIV
- Sexually active transgender persons without HIV
- Persons without HIV who inject drugs

- Persons without HIV who inject drugs
- Persons who have been prescribed non-occupational post-exposure prophylaxis (PEP) and report continued risk behavior, or who have used multiple courses of PEP

Sexually-Active Adults and Adolescents	Persons Who Inject Drugs
Anal or vaginal sex in the past 6 months; **and** HIV-positive sexual partner (especially if partner has unknown or detectable viral load); **or** Recent bacterial STI; **or** History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner; **or** Shares drug preparation or injection equipment
Documented negative HIV test result before prescribing PrEP; **and** No signs/symptoms of acute HIV infection; **and** Normal renal function; **and** No contraindicated medications	

How is PrEP prescribed?

PrEP is FDA-approved to be taken once daily by mouth.[5,6] Full prescribing information is available at https://www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf and https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf.

(See Clinical Providers' Supplement, Section 5: *https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf*)



What is the evidence base for PrEP?

Multiple studies have demonstrated that PrEP is highly effective when taken as prescribed.

Transmission Route	Effectiveness Estimate	Interpretation
Sexual	~99%	Very high levels of adherence to PrEP ensures maximum effectiveness.
Injection drug use	74% – 84%	These estimates are based on tenofovir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily.

For more information on evidence related to daily, consistent, and on-demand PrEP use, visit http://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html.

How important is adherence to PrEP?

To be effective, PrEP requires high levels of adherence. When taken as prescribed, oral PrEP is extremely effective in preventing HIV.[7] A few cases of HIV infection have been reported among MSM whose high adherence to PrEP was verified. These rare cases indicate that the risk of HIV acquisition with high adherence to PrEP is extremely low, but not completely eliminated.

Based on existing research, PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use. For receptive vaginal sex and injection drug use, PrEP reaches maximum protection at up to about 21 days of daily use.

Is PrEP safe?

Yes. PrEP has not caused serious short- or medium-term safety concerns.[8,9,10] F/TDF as PrEP is considered generally safe for pregnant and breastfeeding women.[6] Providers and patients who are or may become pregnant and have concerns should decide together if the risk of ongoing HIV transmission through sex or drug injection is sufficiently high to use PrEP knowing that pregnancy is associated with an increased risk of HIV acquisition.[11]

Since F/TDF and F/TAF are eliminated by the kidneys, PrEP should only be used in patients without renal impairment (see *Renal Function,* below). It should be co-administered with care in patients taking other drugs eliminated by the kidneys (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, valganciclovir, aminoglycosides, and high-dose or multiple NSAIDs). Drugs that decrease renal function may also increase serum concentrations of tenofovir or emtricitabine.[5,6]

Who should not be prescribed PrEP?

- **People with HIV.** Individuals must be confirmed as HIV-negative before initiating PrEP. Excluding persons with acute HIV infection is critically important, as there is a risk of developing resistant HIV if they are inadvertently started on PrEP. F/TDF and F/TAF are appropriate components of a regimen to treat HIV but must be combined with additional antiretrovirals to provide effective treatment.
- **People with renal insufficiency.** Providers should confirm that the patient's estimated creatinine clearance is ≥60 mL/minute (Cockcroft-Gault formula) before initiating F/TDF as PrEP, or ≥30 mL/minute before initiating F/TAF as PrEP.

What baseline assessment is required for individuals beginning PrEP?

HIV Testing

HIV testing is required to confirm that patients do not have HIV infection when they start taking PrEP. While antigen/antibody tests are preferred, at a minimum, clinicians should document a negative antibody test result within the week before initiating (or re-initiating) PrEP medications. The required HIV testing can be accomplished by **(1)** drawing blood and sending the specimen to a laboratory for testing or **(2)** performing a rapid, point-of-care FDA-approved fingerstick blood test. Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests.[12] A listing of FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection are available online at: ***www.cdc.gov/hiv/testing/laboratorytests.html***

Since PrEP is indicated for individuals who report sexual or injection behaviors that place them at risk of HIV acquisition, clinicians should suspect acute HIV infection in persons known to have been exposed recently. Clinicians should solicit a history of signs or symptoms of viral infection during the preceding month or on the day of evaluation in all PrEP candidates with a negative or an indeterminate result on an HIV antibody test.

For patients with signs/symptoms of acute HIV infection within the prior four weeks, the following options are suggested:

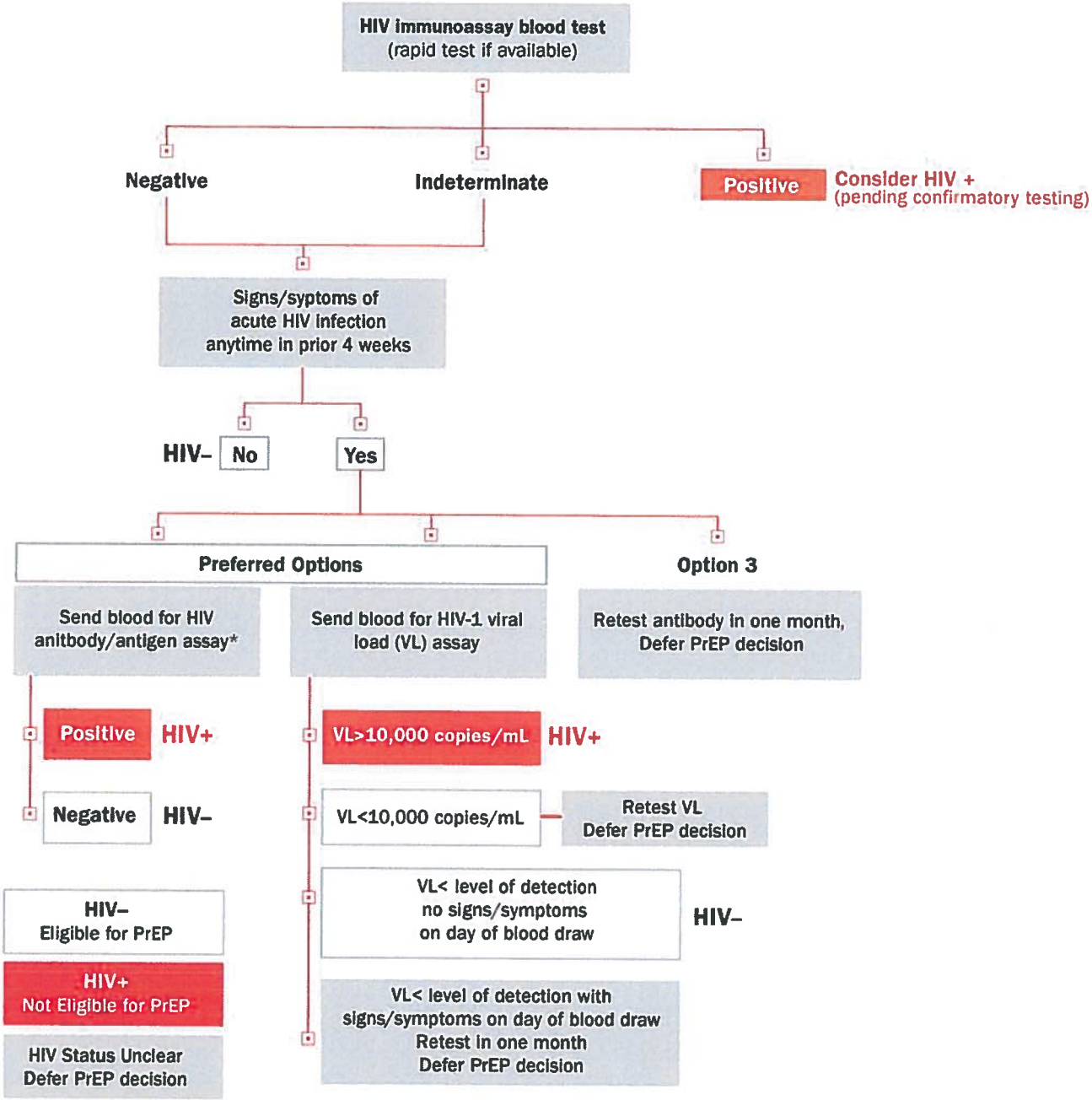
1. Test patient with a combination antibody/antigen assay, ideally with a laboratory-based method. If the test is non-reactive (negative), PrEP can be initiated.
2. Test patient with a viral load (VL) assay. If the patient has a measurable VL <3,000 copies/mL infection is unlikely, but PrEP should be deferred while testing is repeated. If the VL is below the level of detection of the assay, and the patient has no signs/symptoms on that day, PrEP can be initiated.
3. Defer PrEP and retest patient for HIV antibody in one month.

Renal Function

When used as PrEP, TDF-containing regimens can cause decreases in renal function that are typically small and of unknown clinical significance, and that also typically reverse with discontinuation of the drug [5,6]. Occasional cases of acute renal failure, including Fanconi's syndrome, have occurred. [13-20] Therefore, all persons considered for PrEP must have their renal function assessed at treatment initiation as well as periodically thereafter so that PrEP can be stopped, if necessary. Renal function should be assessed using the Cockcroft-Gault formula and the patient's serum creatinine value to calculate an estimated creatinine clearance (eCrCl). F/TDF is approved for use in persons with a eCrCl ≥60 ml/min. F/TAF is approved for use in persons with eCrCl ≥30 ml/min.

Hepatitis B Serology

Emtricitabine and tenofovir can be used to treat HBV, and discontinuation of these medicines can cause rebound hepatitis. HBV infection is not a contraindication to PrEP, but all persons considered for PrEP with F/TDF or F/TAF must be screened for HBV; if they start PrEP, when they stop the medication their liver function can be closely monitored for reactivation of HBV replication that could result in hepatic damage.



** Use only HIV antigen/antibody tests that are approved by FDA for diagnostic purposes*

What additional support and ongoing assessments are required for patients on PrEP?

Prescribe PrEP as part of a combination prevention plan. At minimum, while patients are on PrEP, CDC guidelines recommend:

	Provide the following services:

At 3 months after PrEP initiation:	• Test for HIV.
	• Measure serum creatinine and estimate creatinine clearance.
	• Provide medication adherence and behavioral risk reduction support.
	• Additionally, for
	  ◦ MSM: screen for bacterial STIs*;
	  ◦ Women with reproductive potential: test for pregnancy; and
	  ◦ PWID: assess access to sterile needles/syringes and to drug treatment services.

Every 3 months after the first 3-month follow-up:	• Test for HIV.
	• Provide medication adherence and behavioral risk reduction support.
	• Additionally, for
	  ◦ MSM: screen for bacterial STIs*;
	  ◦ Women with reproductive potential: test for pregnancy; and
	  ◦ PWID: assess access to sterile needles/syringes and to substance use disorder treatment services.

Every 6 months after the first 3-month follow-up:	• Measure serum creatinine and estimate creatinine clearance. • For all sexually active patients: Screen for bacterial STIs*.

*Nucleic Acid Amplification Test (NAAT) to screen for gonorrhea and chlamydia based on anatomic site of exposure; blood test for syphilis.

How will my patients pay for PrEP medication, clinical visits, and lab tests?

Most insurance plans and state Medicaid programs cover PrEP. Prior authorization may be required.

Patient assistance program: There are medication assistance programs that provide free PrEP medications to people with no insurance to cover PrEP care. To learn more, call 855-447-8410 or visit www.getyourprep.com

Co-pay assistance program: Income is not a factor in eligibility. More information is available at: https://www.gileadadvancingaccess.com/ Some states have their own PrEP assistance programs. Some cover medication, some cover clinical visit and lab costs, some cover both. To learn more visit: https://www.nastad.org/prepcost-resources/prep-assistance-programs

How should a patient who acquires HIV infection while taking PrEP be managed?

Once additional laboratory tests have confirmed infection, the following steps should be taken:

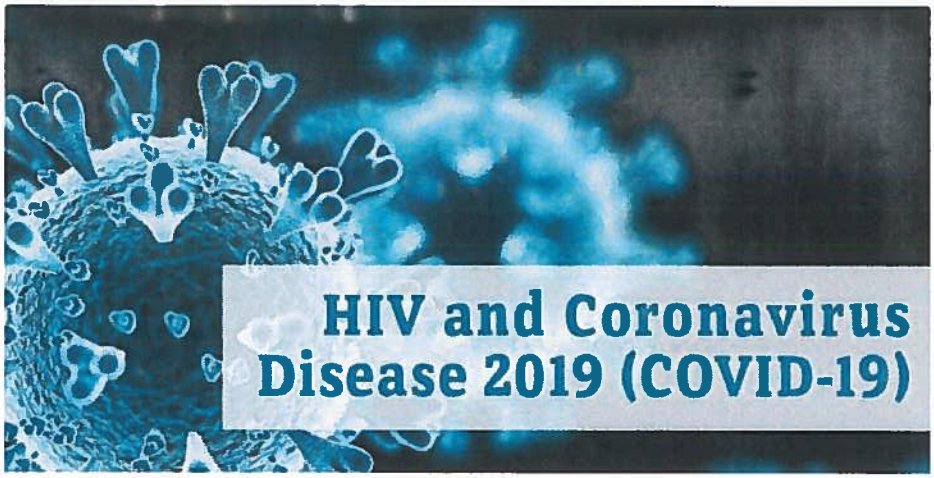
- Initiate treatment or refer for comprehensive HIV care.
- Counsel the patient about how to prevent HIV transmission to others and to improve their own health.
- Report the new HIV infection to the local health department.

To learn more about HIV treatment, see: /preventioniscare

How do I provide

How do I provide PrEP Services during COVID 19?

CDC has developed guidance for providing PrEP when facility-based services and in-person patient-clinician contact is limited. For programs experiencing disruption in PrEP clinical services, CDC offers the following guidance for clinics to consider in the context of local resources and staff availability.



Resources for people at risk or with HIV, clinicians, and public health partners.

1. Clinicians should continue to ensure the availability of PrEP for patients newly initiating PrEP and patients continuing PrEP use.
2. Quarterly HIV testing should be continued for patient safety. Lab-only visits for assessment of HIV infection and other indicated tests for the provision of PrEP are preferred. When these are not available or feasible, CDC recommends considering two additional options:
   - Some laboratories (such as Molecular Testing Labs™) have validated protocols for testing home-collected samples for the panel of tests required for those initiating or continuing PrEP. This laboratory-conducted test is sensitive enough to detect recent HIV infection.
   - The second option is self-testing via an oral swab-based test. Although this type of HIV self-test is usually not recommended for PrEP patients due to its lower sensitivity in detecting recent HIV infection during PrEP use, clinicians could consider use of these tests when other options are not available.
3. When HIV-negative status is confirmed, consider providing a prescription for a 90-day supply of PrEP medication (rather than a 30-day supply with two refills) to minimize trips to the pharmacy and to facilitate PrEP adherence. Several programs are available to help provide affordable PrEP medication including Ready, Set, PrEP , a nationwide program that makes PrEP medications available at no cost to individuals who qualify and lack prescription drug coverage; state drug assistance programs; and Gilead's Medication Assistance Program (MAP) , which assists eligible HIV-negative adults in the United States who require assistance paying for PrEP.
4. If a PrEP clinic is considering closing or suspending services temporarily, health care providers should establish referral relationships with other clinics, telemedicine services, or pharmacies so that clients may remain engaged in PrEP care.

If PrEP clinical services have not been disrupted, providers should continue to follow recommendations outlined in the 2017 PrEP Clinical Guidelines [PDF – 2 MB] and Clinical Providers' Supplement [PDF – 2 MB]. To further ensure safe delivery of critical public health services, CDC has issued guidance for protecting public health workers engaged in public health activities that require face-to-face interaction.

Read the full Dear Colleague Letter on PrEP during COVID-19.

References

1. Centers for Disease Control and Prevention (CDC), US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. CDC website. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018. Accessed June 2, 2019.
2. CDC. Clinical Providers' Supplement. Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States. 2017. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf> Published March 2018. Accessed June 2, 2019.
3. US Preventive Services Task Force. Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement. *JAMA*.2019;321(22):2203–2213.
4. Krakower D, Mayer KH. What primary care providers need to know about preexposure prophylaxis for HIV prevention: a narrative review. *Annals Int Med.* 2012 Oct 2;157(7):490-7.

5. Gilead Sciences. Descovy Package Insert. 2019. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf . Accessed November 7, 2019.
6. Gilead Sciences. Truvada Package Insert. 2016. http://gilead.com/~/media/fles/pdfs/medicines/hiv/truvada/truvada_pi.pdf . Accessed August 8, 2016.
7. Riddell IV J, Amico KR, Mayer KH. HIV Preexposure Prophylaxis: A Review. *JAMA* 2018;319:1261-68.
8. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet* 2014;14:820-9.
9. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399-410.
10. Donnell D, Baeten JM, Bumpus NN, et al. HIV protective efficacy and correlates of tenofovir blood concentrations in a clinical trial of PrEP for HIV prevention. *J Acq Immun Def Syndr* 2014;66:340.
11. Thomson KA, Hughes J, Baeten JM, John-Stewart G, Celum C, Cohen CR, Ngure K, Kiarie J, Mugo N, Heffron R. Increased risk of female HIV-1 acquisition throughout pregnancy and postpartum: a prospective per-coital act analysis among women with HIV-1 infected partners. The Journal of infectious diseases. 2018 Mar 5.
12. Deutsch MB, Glidden DV, Sevelius J, et al. HIV pre-exposure prophylaxis in transgender women: A subgroup analysis of the iPrEx trial. *Lancet HIV* 2015;2(12):e512-e519.
13. Molina J-M, Charreau I, Spire B, et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *Lancet HIV* 2017;4:e402-10.
14. Antoni G, Tremblay C, Charreau I, et al. On-demand PrEP with TDF/FTC remains highly effective among MSM with infrequent sexual intercourse: a sub-study of the ANRS IPERGAY trial. Presented at: IAS Conference on HIV Science; July 23-27, 2017; Paris, France.
15. Saag MS, Benson CA, Gandhi RT, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2018 recommendations of the International Antiviral Society-USA Panel. *JAMA.* 2018;320(4):379-396.
16. Mugwanya KK, Wyatt C, Celum C, et al. Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. JAMA Intern Med. 2015 Feb;175(2):246-54.
17. Mugwanya KK, Wyatt C, Celum C, et al. Reversibility of Glomerular Renal Function Decline in HIV-Uninfected Men and Women Discontinuing Emtricitabine-Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis. *J Acquir Immune Defic Syndr.* 2016 Apr 1;71(4):374-80.
18. Tang EC, Vittinghoff E, Anderson PL, et al. Changes in Kidney Function Associated With Daily Tenofovir Disoproxil Fumarate/Emtricitabine for HIV Preexposure Prophylaxis Use in the United States Demonstration Project. *J Acquir Immune Defic Syndr.* 2018 Feb 1;77(2):193-198.

Appendix C

Colorado State Board of Pharmacy Statewide Protocol

Pre-Exposure and Post-Exposure Prophylaxis of HIV

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the US Centers for Disease Control and Prevention (CDC)[1, 3] and the United States Preventive Services Task Force (USPSTF)[2].

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Colorado

2. Be engaged in the practice of pharmacy

3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist

4. Carry adequate professional liability insurance as determined by the Board

5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.)

6. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.

B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

Pre-Exposure Prophylaxis (PrEP) Protocol

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table I according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within 7 days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

   a. MSM (men who have sex with men)
      - Adult man
      - Without acute or established HIV infection
      - Any male sex partners in past 6 months
      - Not in a monogamous partnership with a recently tested, HIV-negative man

      AND at least one of the following:
      - any anal sex without condoms (receptive or insertive) in the past 6 months
      - A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months

   b. Heterosexually Active Men and Women
      - Adult person
      - Without acute or established HIV infection
      - Any sex with opposite sex partners in past 6 months
      - Not in a monogamous partnership with a recently tested HIV-negative partner

      AND at least one of the following:
      - Is a man who has sex with both women and men (behaviorally bisexual)
      - Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be substantial risk of HIV infection (persons who inject drugs PWID or bisexual male partner)
      - Is in an ongoing sexual relationship with an HIV-positive partner
      - A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

   c. Persons Who Inject Drugs (PWID)
      - Adult person
      - Without acute or established HIV infection
      - Any injection of drugs not prescribed by a clinician in past 6 months

      AND at least one of the following:
      - Any sharing of injection or drug preparation equipment in past 6 months
      - Risk of sexual acquisition (see above)

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:

- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
- CRCL < 60 ml/min

TABLE 1 – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available.

Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Frequency	Duration of Therapy	Notes
FTC/TDF emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <60 ml/min.
FTC/TAF emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert Table 5.

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

- PrEP cannot be started without a negative HIV test at baseline.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.
- PrEP refills will not be authorized past the initial 30 day supply if recommended baseline testing is not done by one of the above mechanisms.

Test	Frequency	CDC recommendations	Notes
HIV	Baseline + Every 3 months	**Required**	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + At 3 mo if symptomatic. Every 6 months if asymptomatic	Recommended	If positive – refer for care
Serum creatinine	Baseline, at 3 months, and thereafter every 6 months	Recommended	If CRCL <60 ml/min, cannot use FTC/TDF If CRCL <30 ml/min cannot use FTC/TAF
Hepatitis B screening	Baseline	Recommended	If positive – refer for care
Bone health		Optional	
Need to continue PrEP	Annually	Recommended if at continued risk	Discuss with patient

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted diseases

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- If a female patient becomes pregnant while on PrEP

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

* What is this for?

[1] CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

2 USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. nPEP must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. nPEP should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. PEP providers in Colorado include the STD Clinic at Denver Public Health (303.602.3540) and local emergency departments (CDPHE to comment).

If the following criteria are met, antiretroviral agents in Table 1 are recommended:

- The exposure must have occurred within 72 hours

- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.

- Exposure to a source individual known to be HIV-positive. Exposure of:

    - Vagina

    - Rectum

    - Eye

- Mouth
- Other mucous membranes
- Nonintact skin
- Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

WITH

- Blood
- Semen
- Vaginal secretions
- Rectal secretions
- Breast milk
- Any body fluid visibly contaminated with blood

- Exposure types with the highest risk of transmission of HIV are:
  - Needle sharing during injection drug use
  - Percutaneous needle stick
  - Receptive anal intercourse
- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 1 may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services MUST be contacted.

Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at https://www.ccasa.org/gethelp/health-related-organizations/

- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-844-CO-4-KIDS.

TABLE 1 – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

Medication	Age/Weight	Dose	Duration of Therapy	Notes
PREFERRED REGIMEN				
emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) PLUS raltegravir 400mg	≥ 13 years	Once daily #28 no refills Twice daily #56 no refills	28 days	Dosing adjustments with renal dysfunction if CrCL <60 ml/min.
OR Dolutegravir 50mg		Once daily #28 no refills		Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used.

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is.

- Ask the following screening question:

  - Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.
- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

Test	Frequency	CDC recommendations	Notes
HIV	Baseline + Post-exposure at week 4-6, and months 3 and 6	**Required**	If positive, refer.
STI screenings (syphilis, gonorrhea, chlamydia)	Baseline	Recommended	If positive – refer for care
Serum creatinine	Baseline + @4-6 weeks.	Recommended	
ALT/AST	Baseline + @4-6 weeks.	Recommended	
Hepatitis B screening	Baseline + 6 mo	Recommended	If positive – refer. If negative and clinically appropriate, vaccinate
Hepatitis C screening	Baseline + 6 mo	Recommended	If positive - refer
Pregnancy	Baseline + @4-6 weeks.	Recommended	Pregnancy is not a contraindication to NPEP

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases

- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.

- The pharmacist will also follow all documentation rules in 17.00

Referrals:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care

- Signs of symptoms of acute drug toxicities or serious side effects

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

[3] CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use or Other Nonoccupational Exposure to HIV – United States, 2016. Available at: https://stacks.cdc.gov/view/cdc/38856

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE

What's New in the Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update – A Clinical Practice Guideline?

(Published online March 2018)

The Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 was published in an electronic format in July 2014 so that it could be updated as relevant changes in supporting evidence became available. The Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2016: Update – A Clinical Practice Guideline includes revisions to several sections. These revisions are highlighted throughout the document and are intended solely to update the developing evidence base or to clarify specific points in clinical care. No changes were made to the graded recommendations for the use of PrEP in the US.

Evidence of the Safety and Efficacy of Antiretroviral Prophylaxis

Based on an updated systematic review of publications through June 2017, data from trials and open-label studies were added to the text summary and evidence tables.

Identifying Indications for PrEP

In Box B3 (recommended indications for PrEP use by injection drug users) we deleted whether they had been in drug treatment in the prior 6 months as this was causing confusion for many clinicians.

Laboratory Tests and other Diagnostic Procedures

We replaced the HIV test characteristic tables previously in appendices with a link to a CDC website that is more frequently updated.

The figure and text on testing by clinicians to determine HIV status for PrEP provision (including detection of acute HIV infection) was revised to include a preference for antigen/antibody testing whenever available (rather than antibody-only tests) and use of a 3,000 copies/ml cut-off for suspected false-positive viral load tests.

Additional information about hepatitis C screening associated with provision of PrEP is provided, consistent with the 2017 American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) guidance.

Providing PrEP

Ledipasvir/sofosbuvir was added to the table (10) of drug interactions

Tenofovir alafenamide (TAF) was added to the section "What not to use"

We revised the clinical follow up schedule to include STI testing for asymptomatic MSM at high risk for recurrent STIs (e.g., those with recent STIs or multiple sex partners) at the 3 month visit in addition to testing for all symptomatic sexually-active persons. This is consistent with 2015 STD guidelines recommendation for STD screening every 3-6 months with multiple sex partners (https://www.cdc.gov/std/tg2015/tg-2015-print.pdf).

Minor revisions were also made to correct typos, add references, and update content from cited guidelines and source materials.

Disclaimers:

All material in this publication is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

References to non-CDC sites on the Internet are provided as a service to readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed were current as of the date of publication.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Suggested Citation:

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

For more clinical advice about PrEP guidelines:

- call the National Clinicians Consultation Center PrEPline at 855-448-7737 or
- go to their website at http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/

Table of Contents

List of Tables, Figures, and Boxes.....6

Abbreviations (In Guideline and Clinical Provider Supplement).....7

Summary.....9

Introduction.....12

Evidence of Need for Additional HIV Prevention Methods.....13

Evidence of the Safety and Efficacy of Antiretroviral Prophylaxis.....14

Published Trials of Antiretroviral Preexposure Prophylaxis Among Men Who Have Sex with Men.....14

iPrEx (Preexposure Prophylaxis Initiative) Trial.....14

US MSM Safety Trial.....15

Adolescent Trials Network (ATN) 082.....16

Ipergay (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays).....16

Published Observational and Open-Label Studies of Antiretroviral Preexposure Prophylaxis Among Men Who Have Sex with Men.....17

iPrEx Open-Label Extension (OLE) Study.....17

PROUD.....17

Kaiser Permanente.....18

Demo Project.....18

Ipergay Open-Label Extension (OLE) Study.....18

Published Trials of Antiretroviral Preexposure Prophylaxis Among Heterosexual Men an Women.....19

Partners PrEP Trial.....19

TDF2 Trial.....19

FEM-PrEP Trial.....20

Phase 2 Trial of Preexposure Prophylaxis with Tenofovir Among Women in Ghana, Cameroon, and Nigeria..... 21

VOICE (Vaginal and Oral Interventions to Control the Epidemic) Trial.....21

Published Trial of Antiretroviral Preexposure Prophylaxis Among Persons Who Inject Drugs..22

Bangkok Tenofovir Study (BTS).....22

Published Observational and Open-Label Studies of Antiretroviral Preexposure Prophylaxis Among Persons Who Inject Drugs.....23

Bangkok Tenofovir Study (BTS) OLE..... 23

Identifying Indications for PrEP.....31

Assessing Risk of Sexual HIV Acquisition.....31

Assessing Risk of HIV Acquisition Through Injection Practices.....35

Laboratory Tests and Other Diagnostic Procedures.....36

HIV Testing.....36

Acute HIV Infection.....37

Renal Function.....39

Hepatitis Serology.....40

Testing for Sexually Transmitted Infections 42

Providing PrEP.....42

Goals of PrEP Therapy.....42

Indicated Medication.....43

What Not to Use.....44

Time to achieving protection.....44

Managing side effects.....45

Clinical Follow-Up and Monitoring.....45

Optional Assessments.....46

Bone Health.....46

Therapeutic Drug Monitoring.....46

Persons with Documented HIV Infection.....47

Discontinuing PrEP.....47

Special Clinical Considerations.....48

Women Who Become Pregnant or Breastfeed While Taking PrEP Medication.....48

Patients with Chronic Active Hepatitis B Virus Infection.....49

Patients with Chronic Renal Failure.....50

Adolescent Minors.....50

Nonoccupational Postexposure Prophylaxis.....50

Improving Medication Adherence.....51

Reducing HIV Risk Behaviors.....54

Financial Case-Management Issues for PrEP.....55

Decision Support, Training and Technical Assistance.....55

Related DHHS Guidelines.....56

Appendices.....58

Appendix 1 Grading of Strength of Recommendations and Quality of Evidence.....59

References.....61

List of Tables, Figures, and Boxes

Table 1 Summary of Guidance for PrEP Use **11**

Table 2 PrEP Evidence Summary—GRADE Overall Evidence Quality RCTs **24**

Table 3 PrEP Evidence Summary— HIV Incidence Findings RCTs **25**

Table 4 PrEP Evidence Summary—Measures of Efficacy by Medication Adherence RCTs **26**

Table 5 PrEP Evidence Summary— Safety and Toxicity RCTs **27**

Table 6 PrEP Evidence Summary— HIV Resistance Findings RCTs **28**

Table 7 PrEP Evidence Summary— Open-Label Studies **29**

Table 8 Clinical Signs and Symptoms of Acute (Primary) HIV Infection **36**

Table 9 Hepatitis Screening Serology **38**

Table 10 Recommended Oral PrEP Medications **40**

Table 11 PrEP Medication Drug Interactions **40**

Table 12 Rating Scheme for Recommendations **54**

Table 13 Criteria for Rating Quality of Scientific Evidence **55**

Figure Clinician Determination of HIV Status for PrEP Provision **36**

Box A Risk Behavior Assessments **30**

Box A1 Risk Behavior Assessment for MSM 30

Box A2 Risk Behavior Assessment for Heterosexually Active Men and Women 31

Box A3 Risk Behavior Assessment for Injection Drug Users 33

Box B Recommended Indications for PrEP Use **33**

Box B1 Recommended Indications for PrEP Use by MSM 33

Box B2 Recommended Indications for PrEP Use by Heterosexually Active Men and Women 33

Box B3 Indications for PrEP Use by Injection Drug Users 34

Box C Cockcroft-Gault Formulas **38**

Box D Key Components of Medication Adherence Counseling **49**

Box E Key Components of Behavioral Risk Reduction Counseling **51**

Abbreviations (In Guideline and Clinical Providers' Supplement)

ACTG	AIDS Clinical Trials Group
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immunodeficiency syndrome
BMD	bone mineral density
CDC	Centers for Disease Control and Prevention
CPT	common procedural terminology
DEXA	dual-emission X-ray absorptiometry
DHAP	Division of HIV/AIDS Prevention, CDC
DHHS	Department of Health and Human Services
eCrCl	estimated creatinine clearance rate (ml/min)
EIA	enzyme-linked immunoassay
FDA	Food and Drug Administration
FHI	Family Health International
FTC	emtricitabine (trade name Emtriva)
GEM	Guidelines Elements Model
GLIA	GuideLine Implementability Appraisal
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
ICD	International Classification of Diseases
IDU	injection drug users (also called PWID)
IFA	indirect immunofluorescence assay
IHS	Indian Health Service
IQR	interquartile range
MSM	men who have sex with men
MTN	Microbicide Trials Network
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NGC	National Guidelines Clearinghouse
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
nPEP	nonoccupational postexposure prophylaxis
NSAID	non-steroidal anti-inflammatory drug
NQMC	National Quality Measures Clearinghouse
OHAP	Office of HIV/AIDS Policy, DHHS
ONAP	Office of National AIDS Policy
ONDCP	Office of National Drug Control Policy
OPA	Office of Population Affairs, DHHS

PCR	polymerase chain reaction
PEP	postexposure prophylaxis
PHS	(U.S.) Public Health Service
PWID	persons who inject drugs (also called IDU)
PrEP	preexposure prophylaxis
SAMHSA	Substance Abuse and Mental Health Services Administration
STD	sexually transmitted disease
STI	sexually transmitted infection
TB	tuberculosis
TDF	tenofovir disoproxil fumarate (trade name Viread®)
TAF	tenofovir alafenamide
TDM	therapeutic drug monitoring
UNAIDS	Joint United National Programme on HIV/AIDS
VA	Veterans Administration
WHO	World Health Organization

Summary

Preexposure Prophylaxis for HIV Prevention in the United States – 2017 Update: A Clinical Practice Guideline provides comprehensive information for the use of daily oral antiretroviral preexposure prophylaxis (PrEP) to reduce the risk of acquiring HIV infection in adults. The key messages of the guideline are as follows:

- Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore,
    - PrEP is recommended as one prevention option for sexually-active adult MSM (men who have sex with men) at substantial risk of HIV acquisition **(IA)**[1]
    - PrEP is recommended as one prevention option for adult heterosexually active men and women who are at substantial risk of HIV acquisition. **(IA)**
    - PrEP is recommended as one prevention option for adult persons who inject drugs (PWID) (also called injection drug users [IDU]) at substantial risk of HIV acquisition. **(IA)**
    - PrEP should be discussed with heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) as one of several options to protect the uninfected partner during conception and pregnancy so that an informed decision can be made in awareness of what is known and unknown about benefits and risks of PrEP for mother and fetus **(IIB)**
- Currently the data on the efficacy and safety of PrEP for adolescents are insufficient. Therefore, the risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors. **(IIIB)**
- Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately before PrEP is prescribed. **(IA)**
- The only medication regimen approved by the Food and Drug Administration and recommended for PrEP with all the populations specified in this guideline is daily TDF 300 mg co-formulated with FTC 200 mg (Truvada) **(IA)**
    - TDF alone has shown substantial efficacy and safety in trials with PWID and heterosexually active adults and can be considered as an alternative regimen for these populations, but not for MSM, among whom its efficacy has not been studied. **(IC)**
    - The use of other antiretroviral medications for PrEP, either in place of or in addition to TDF/FTC (or TDF) is not recommended. **(IIIA)**
    - The prescription of oral PrEP for coitally-timed or other noncontinuous daily use is not recommended. **(IIIA)**

[1] See Appendix 1, Grading of Strength of Recommendations and Quality of Evidence (Tables 12-13)

- HIV infection should be assessed at least every 3 months while patients are taking PrEP so that those with incident infection do not continue taking it. The 2-drug regimen of TDF/FTC is inadequate therapy for established HIV infection, and its use may engender resistance to either or both drugs. **(IA)**
- Renal function should be assessed at baseline and monitored at least every 6 months while patients are taking PrEP so that those in whom renal failure is developing do not continue to take it. **(IIIA)**
- When PrEP is prescribed, clinicians should provide access, directly or by facilitated referral, to proven effective risk-reduction services. Because high medication adherence is critical to PrEP efficacy but was not uniformly achieved by trial participants, patients should be encouraged and enabled to use PrEP in combination with other effective prevention methods. **(IIIA)**

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Persons Who Inject Drugs
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI† High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI‡ High number of sex partners History of inconsistent or no condom use Commercial sex work In high HIV prevalence area or network	HIV-positive injecting partner Sharing injection equipment
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 3-6 months, test for bacterial STIs		
	Do oral/rectal STI testing	For women, assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

† Gonorrhea, chlamydia, syphilis for MSM including those who inject drugs

‡ Gonorrhea, syphilis for heterosexual women and men including those who inject drugs

3127

Introduction

Recent findings from several clinical trials have demonstrated safety[1] and a substantial reduction in the rate of HIV acquisition for men who have sex with men (MSM)[2], men and women in heterosexual HIV-discordant couples[3], and heterosexual men and women recruited as individuals[4] who were prescribed daily oral antiretroviral preexposure prophylaxis (PrEP) with a fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC). In addition, one clinical trial among persons who injection drugs (PWID) (also called injection drug users [IDU][5] and one among men and women in heterosexual HIV-discordant couples[3] have demonstrated substantial efficacy and safety of daily oral PrEP with TDF alone. The demonstrated efficacy of PrEP was in addition to the effects of repeated condom provision, sexual risk-reduction counseling, and the diagnosis and treatment of sexually transmitted infection (STI), all of which were provided to trial participants, including those in the drug treatment group and those in the placebo group. In July 2012, after reviewing the available trial results, the U.S. Food and Drug Administration (FDA) approved an indication for the use of Truvada[§] (TDF/FC) "in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk"[6,7].

On the basis of these trial results and the FDA approval, the U.S. Public Health Service recommends that clinicians evaluate their male and female patients who are sexually active or who are injecting illicit drugs and consider offering PrEP as one prevention option to those whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.

The evidence base for the 2014 recommendations were derived from a systematic search and review of published literature. To identify all PrEP safety and efficacy trials pertaining to the prevention of sexual and injection acquisition of HIV, a search of the clinical trials registry (http://www.clinicaltrials.gov) was performed by using combinations search terms (preexposure prophylaxis, pre-exposure prophylaxis, PrEP, HIV, Truvada, tenofovir, and antiretroviral). In addition, the same search terms were used to search conference abstracts for major HIV conferences (e.g., International AIDS Conference, Conference on Retroviruses and Opportunistic Infections) for the years 2009-2013. These same search terms were used to search PubMed and Web of Science databases for the years 2006-2013. Finally, a review of references from published PrEP trial data and the data summary prepared by FDA for its approval decision[8] confirmed that no additional trial results were available. For the 2017 update, the systematic review of published literature was updated through June 2017 and expanded to include the terms *chemoprophylaxis* and *chemoprevention* and searches of the MEDLINE, Embase, CINAHL, and Cochrane Library database in addition to those used in 2014. The results of this systematic review were crosschecked for completeness with the review conducted by the World Health

[§] Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Organization[9]. For additional information about the systematic review process, see the Clinical Providers' Supplement, Section 14 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf

Potential conflicts of interest: CDC and individual employees involved in the guideline development process are named in US government patents and patent applications related to methods for HIV prophylaxis.

This publication provides a comprehensive clinical practice guideline for the use of PrEP for the prevention of HIV infection in the United States. It incorporates and extends information provided in interim guidance for PrEP use with MSM[10], with heterosexually active adults[11], and with PWID (also called IDU)[12]. Currently, prescribing daily oral PrEP with TDF/FTC is recommended as one prevention option for MSM, heterosexual men, heterosexual women, and PWID at substantial risk of HIV acquisition. As the results of additional PrEP clinical trials and studies in these and other populations at risk of HIV acquisition become known, this guideline will be updated.

The intended users of this guideline include

- primary care clinicians who provide care to persons at risk of acquiring HIV infection
- clinicians who provide substance abuse treatment
- infectious disease and HIV treatment specialists who may provide PrEP or serve as consultants to primary care physicians about the use of antiretroviral medications
- health program policymakers.

Evidence of Need for Additional HIV Prevention Methods

Approximately 40,000 people in the United States are infected with HIV each year[13]. From 2008 through 2014, estimated annual HIV incidence declined 18% overall but progress was uneven. Although declines occurred among heterosexuals, PWID, and white MSM, no decline was observed in the estimated number of annual HIV infections among black MSM and an increase was documented among Latino MSM[13]. In 2015, 67% of the 39,513 newly diagnosed HIV infections were attributed to male-male sexual activity without injection drug use, 3% to male-male sexual activity with injection drug use, 24% to male-female sexual contact without injection drug use, and 6% to injection drug use. Among the 24% of persons with newly diagnosed HIV infection attributed to heterosexual activity, 64% were African-American women and men[14]. These data indicate a need for additional methods of HIV prevention to further reduce new HIV infections, especially (but not exclusively) among young adult and adolescent MSM of all races and Hispanic/Latino ethnicity and for African American heterosexuals (populations with higher HIV prevalence and at higher risk of HIV infection among those without HIV infection).

Evidence of the Safety and Efficacy of Antiretroviral Prophylaxis

The biological plausibility and the short-term safety of antiretroviral use to prevent HIV acquisition in other exposure situations have been demonstrated in 2 studies conducted prior to the PrEP trials. In a randomized placebo-controlled trial, perinatal transmission was reduced 68% among the HIV-infected women who received zidovudine during pregnancy and labor and whose infants received zidovudine for 6 weeks after birth[15]. That is, these infants received both preexposure and postexposure prophylaxis. In 1995, investigators used case-control surveillance data from health-care workers to demonstrate that zidovudine provided within 72 hours after percutaneous exposure to HIV-infected blood and continued for 28 days (PEP, or postexposure prophylaxis) was associated with an 81% reduction in the risk of acquiring HIV infection[16-18].

Evidence from these human studies of blood-borne and perinatal transmission as well as studies of vaginal and rectal exposure among animals suggested that PrEP (using antiretroviral drugs) could reduce the risk of acquiring HIV infection from sexual and drug-use exposures. Clinical trials were launched to evaluate the safety and efficacy of PrEP in populations at risk of HIV infection through several routes of exposure. The results of completed trials and open label or observational studies published as of June 2017 are summarized below. See also Tables 2-7. The quality of evidence in each study was assessed using GRADE criteria (http://www.gradeworkinggroup.org/FAQ/evidence_qual.htm) and the strength of evidence for all studies relevant to a specific recommendation was assessed by the method used in the DHHS antiretroviral treatment guidelines (See Appendix 1)

Published Trials of Antiretroviral Preexposure Prophylaxis Among Men Who Have Sex with Men

iPrEx (Preexposure Prophylaxis Initiative) Trial

The iPrEx study[2] was a phase 3, randomized, double-blind, placebo-controlled trial conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the United States among men and male-to-female transgender adults who reported sex with a man during the 6 months preceding enrollment. Participants were randomly assigned to receive a daily oral dose of either the fixed-dose combination of TDF and FTC or a placebo. All participants (drug and placebo groups) were seen every 4 weeks for an interview, HIV testing, counseling about risk- reduction and adherence to PrEP medication doses, pill count, and dispensing of pills and condoms. Analysis of data through May 1, 2010, revealed that after the exclusion of 58 participants (10 later determined to be HIV- infected at enrollment and 48 who did not have an HIV test after enrollment), 36 of 1,224 participants in the TDF/FTC group and 64 of 1,217 in the placebo group had acquired HIV infection. Enrollment in the TDF/FTC group was associated with a 44% reduction in the risk of HIV acquisition (95% CI, 15-63). The reduction was greater in the as-treated analysis: at the visits at which adherence was ≥50% (by self-report and pill count/dispensing), the reduction in HIV acquisition was 50% (95% CI, 18-70). The reduction in the risk of HIV acquisition was

73% at visits at which self-reported adherence was ≥90% (95% CI, 41-88) during the preceding 30 days. Among participants randomly assigned to the TDF/FTC group, plasma and intracellular drug-level testing was performed for all those who acquired HIV infection during the trial and for a matched subset who remained HIV- uninfected: a 92% reduction in the risk of HIV acquisition (95% CI, 40-99) was found in participants with detectable levels of TDF/FTC versus those with no drug detected.

Generally, TDF/FTC was well tolerated, although nausea in the first month was more common among participants taking medication than among those taking placebo (9% versus 5%). No differences in severe (grade 3) or life-threatening (grade 4) adverse laboratory events were observed between the active and placebo group, and no drug-resistant virus was found in the 100 participants infected after enrollment. Among 10 participants who were HIV-negative at enrollment but later found to have been infected before enrollment, FTC-resistant virus was detected in 2 of 2 men in the active group and 1 of 8 men in the placebo group. Compared to participant reports at baseline, over the course of the study participants in both the TDF/FTC and placebo groups reported fewer total numbers of sex partners with whom the participants had receptive anal intercourse and higher percentages of partners who used condoms.

In the original iPrEx publication[2], of 2,499 MSM, 29 identified as female (i.e., transgender women). In a subsequent subgroup analysis[19], men were categorized as transgender women (n=339) if they were born male and either identified as women (n=29), identified as transgender (n=296), or identified as male and used feminizing hormones (n=14). Using this expanded definition, among transgender women, no efficacy of PrEP was demonstrated. There were 11 infections among the PrEP group and 10 in the placebo group (HR 1.1, 95% CI: 0.5-2.7). By drug level testing (*always* versus *less than always*), compared with MSM, transgender women had less consistent PrEP use OR 0.39 (95% CI: 0.16-0.96). In the subsequent open-label extension study (see below), one transgender woman seroconverted while receiving PrEP and one seroconversion occurred in a woman who elected not to use PrEP.

US MSM Safety Trial

The US MSM Safety Trial[1] was a phase 2 randomized, double-blind, placebo-controlled study of the clinical safety and behavioral effects of TDF for HIV prevention among 400 MSM in San Francisco, Boston, and Atlanta. Participants were randomly assigned 1:1:1:1 to receive daily oral TDF or placebo immediately or after a 9- month delay. Participants were seen for follow-up visits 1 month after enrollment and quarterly thereafter. Among those without directed drug interruptions, medication adherence was high: 92% by pill count and 77% by pill bottle openings recorded by Medication Event Monitoring System (MEMS) caps. Temporary drug interruptions and the overall frequency of adverse events did not differ significantly between TDF and placebo groups. In multivariable analyses, back pain was the only adverse event associated with receipt of TDF. In a subset of men at the San Francisco site (n=184) for whom bone mineral density (BMD) was assessed, receipt of TDF was associated with small decrease in BMD (1% decrease

at the femoral neck, 0.8% decrease for total hip)[20]. TDF was not associated with reported bone fractures at any anatomical site. Among 7 seroconversions, no HIV with mutations associated with TDF resistance was detected. No HIV infections occurred while participants were being given TDF; 3 occurred in men while taking placebo, 3 occurred among men in the delayed TDF group who had not started receiving drug; 1 occurred in a man who had been randomly assigned to receive placebo and who was later determined to have had acute HIV infection at the enrollment visit.

Adolescent Trials Network (ATN) 082

ATN 082[21] was a randomized, blinded, pilot feasibility study comparing daily PrEP with TDF/FTC with and without a behavioral intervention (Many Men, Many Voices) to a third group with no pill and no behavioral intervention. Participants had study visits every 4 weeks with audio-computer assisted interviews (ACASI), blood draws, and risk-reduction counseling. The outcomes of interest were acceptability of study procedures, adherence to pill-taking, safety of TDF/FTC, and levels of sexual risk behaviors among a population of young (ages 18-22 years) MSM in Chicago. One hundred participants were to be followed for 24 weeks, but enrollment was stopped and the study was unblinded early when the iPrEx study published its efficacy result. Sixty-eight participants were enrolled. By drug level detection, adherence was modest at week 4 (62%), and declined to 20% by week 24. No HIV seroconversions were observed.

Ipergay (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays)

The results of a randomized, blinded, trial of non-daily dosing of TDF/FTC or placebo for HIV preexposure prophylaxis has also been published[22] and is included here for completeness, although non-daily dosing is not currently recommended by the FDA or CDC.

Four-hundred MSM in France and Canada were randomized to a complex peri-coital dosing regimen that involved taking 1) 2 pills (TDF/FTC or placebo) between 2 and 24 hours before sex, 2) 1 pill 24 hours after the first dose, 3) 1 pill 48 hours after the first dose, 4) continuing daily pills if sexual activity continues until 48 hours after the last sex. If more than a 1 week break occurred since the last pill, retreatment initiation was with 2 pills before sex or if less than a 1 week break occurred since the last pill, retreatment initiation was with 1 pill before sex. Each pre-sex dose was then followed by the 2 post-sex doses. Study visits were scheduled at 4 and 8 weeks after enrollment, and then every 8 weeks. At study visits, participants completed a computer-assisted interview, had blood drawn, received adherence and risk reduction counseling, received diagnosis and treatment of STIs as indicated, and had a pill count and a medication refill. Following an interim analysis by the data and safety monitoring board at which efficacy was determined, the placebo group was discontinued and all study participants were offered TDF/FTC. In the blinded phase of the trial, efficacy was 86% (95% CI: 40-98). By self-report,

patients took a median of 15 pills per month. By measured plasma drug levels in a subset of those randomized to TDF/FTC, 86% had TDF levels consistent with having taken the drug during the previous week.

Because of the high frequency of sex and therefore of pill-taking among those in this study population, it is not yet known whether the regimen will work if taken only a few hours or days before sex, without any buildup of the drug in rectal tissue from prior use. Studies suggest that it may take days, depending on the site of sexual exposure, for the active drug in PrEP to build up to an optimal level for preventing HIV infection. No data yet exist on how effective this regimen would be for heterosexual men and women, and persons who inject drugs, or on adherence to this relatively complex PrEP regimen outside a trial setting. IPERGAY findings, combined with other recent research, suggest that even with less than perfect daily adherence, PrEP may still offer substantial protection for MSM if taken consistently.

Daily oral PrEP with TDF/FTC is recommended as one HIV prevention option for sexually-active MSM at substantial risk of HIV acquisition because the iPrEx trial presents evidence of its safety and efficacy in this population, especially when medication adherence is high. **(IA)**

Published Observational and Open-Label Studies of Antiretroviral Preexposure Prophylaxis Among Men Who Have Sex with Men

iPrEx Open-Label Extension (OLE) Study

Persons previously enrolled in the iPrEx, ATN 082, and CDC safety PrEP clinical trials were enrolled in a 72 week open-label study and were offered PrEP free of charge[23]. Seventy-six percent of 1,603 persons (1,428 MSM and 175 transgender women) enrolled received PrEP. HIV incidence among those receiving PrEP was 1.8 per 100 person-years (py) versus 2.6 per 100 py in those concurrently not choosing PrEP (HR 0.51, 95% CI: 0.26-1.01), adjusted for baseline sexual behaviors. Among those receiving PrEP, by dried blood spot drug levels, there were no infections in persons with drug levels associated with having taken 4 or more doses per week ($p<0.0001$) compared with those taking < 2 doses per week.

PROUD Open-Label Extension (OLE) Study

PROUD was an open-label, randomized, wait-list controlled trial designed for MSM attending sexual health clinics in England[24]. A pilot was initiated to enroll 500 MSM, in which 275 men were randomized to receive daily oral TDF/FTC immediately, and 269 were deferred to start after 1 year. At an interim analysis, the data monitoring committee stopped the trial early for efficacy at an interim analysis and recommended that all deferred participants be offered PrEP. Follow-up was completed for 94% of those in the immediate PrEP arm and 90% of those in the deferred arm. PrEP efficacy was 86% (90% CI: 64-96).

Kaiser Permanente Observational Study

An evaluation of a specialized PrEP program provided at the Kaiser Permanente San Francisco Medical Center[25] reported on a cohort of 653 MSM, 3 heterosexual women, and 1 transgender man (with male sexual partners) who initiated PrEP between July 2012 and February 2015. Of these, 20 restarted PrEP after discontinuing it during the study period. The mean duration of use was 7.2 months. No HIV diagnoses were made during 388 py of follow-up on PrEP. No medication adherence measures were reported. After 12 months of use, 50% of PrEP users had received a diagnosis of one or more STI (95% CI: 26-35). In a recent report on PrEP patients seen at this center, as of February 2017, there were no HIV infections during 5104 py of PrEP use while they were being prescribed medication[26].

Demo Project Open-Label Study

In this demonstration project, conducted at 3 community-based clinics in the United States[27], MSM (n = 430) and transgender women (n=5) were offered daily oral TDF/FTC free of charge for 48 weeks. All patients received HIV testing, brief counseling, clinical monitoring, and STI diagnosis and treatment at quarterly follow-up visits. A subset of men underwent drug level monitoring with dried-blood spot testing and protective levels (associated with ≥4 doses per week) were high (80.0%-85.6%) at follow-up visits across the sites. STI incidence remained high but did not increase over time. Two men became infected (HIV incidence 0.43 infections per 100 py, 95% CI: 0.05-1.54), both of whom had drug levels consistent with having taken fewer than 2 doses per week at the visit when seroconversion was detected.

Ipergay Open-Label Extension (OLE) Study

Findings have been reported from the open-label phase of the Ipergay trial that enrolled 361 of the original trial participants[28]. All of the open-label study participants were provided peri-coital PrEP as in the original trial. After a mean follow-up time of 18.4 months (IQR: 17.7-19.1), the HIV incidence observed was 0.19 per 100 py which, compared to the incidence in the placebo group of the original trial (6.60 per 100 py), represented a 97% (95% CI: 81-100) relative reduction in HIV incidence. The one participant who acquired HIV had not taken any PrEP in the 30 days before his reactive HIV test and was in an ongoing relationship with an HIV positive partner. Of 336 participants with plasma drug levels obtained at the 6-month visit, 71% had tenofovir detected. By self-report, PrEP was used at the prescribed dosing for the most recent sexual intercourse by 50% of participants, with suboptimal dosing by 24%, and not used by 26%. Reported condomless receptive anal sex at most recent sexual intercourse increased from 77% at baseline to 86% at the 18-month follow-up visit (p=0.0004). The incidence of a first bacterial STI in the observational study (59.0 per 100 py) was not higher than that seen in the randomized trial (49.1 per 100 py) (p=0.11).

The frequency of pill-taking in the open label study population was higher (median 18 pills per month) than that in the original trial (median 15 pills per month), Therefore it remains unclear

whether the regimen will be highly protective if taken only a few hours or days before sex, without any buildup of the drug from prior use.

Published Trials of Antiretroviral Preexposure Prophylaxis Among Heterosexual Men and Women

Partners PrEP Trial

The Partners PrEP trial[3,29] was a phase 3 randomized, double-blind, placebo-controlled study of daily oral TDF/FTC or TDF for the prevention of acquisition of HIV by the uninfected partner in 4,758 HIV-discordant heterosexual couples in Uganda and Kenya. The trial was stopped after an interim analysis in mid-2011 showed statistically significant efficacy in the medication groups (TDF/FTC or TDF) compared with the placebo group. In 48% of couples, the infected partner was male. HIV-positive partners had a median CD4 count of 495 cells/μL and were not being prescribed antiretroviral therapy because they were not eligible by local treatment guidelines. Participants had monthly follow-up visits and the study drug was discontinued among women who became pregnant during the trial.

Adherence to medication was very high: 98% by pills dispensed, 92% by pill count, and 82% by plasma drug-level testing among randomly selected participants in the TDF and TDF/FTC study groups. Rates of serious adverse events and serum creatinine or phosphorus abnormalities did not differ by study group. Modest increases in gastrointestinal symptoms and fatigue were reported in the antiretroviral medication groups compared with the placebo group, primarily in the first month of use. Among participants of both sexes combined, efficacy estimates for each of the 2 antiretroviral regimens compared with placebo were 67% (95% CI, 44-81) for TDF and 75% (95% CI, 55-87) for TDF/FTC. Among women, the estimated efficacy was 71% for TDF and 66% for TDF/FTC. Among men, the estimated efficacy was 63% for TDF and 84% for TDF/FTC. Efficacy estimates by drug regimen were not statistically different among men, women, men and women combined, or between men and women. In a Partners PrEP substudy that measured plasma TDF levels among participants randomly assigned to receive TDF/FTC, detectable drug was associated with a 90% reduction in the risk of HIV acquisition. TDF- or FTC- resistant virus was detected in 3 of 14 persons determined to have been infected when enrolled (2 of 5 in the TDF group; 1 of 3 in the TDF/FTC group)[8]. No TDF or FTC resistant virus was detected among those infected after enrollment. Among women, the pregnancy rate was high (10.3 per 100 py) and rates did not differ significantly between the study groups.

TDF2 Trial

The Botswana TDF2 Trial[4], a phase 2 randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF/FTC, enrolled 1,219 heterosexual men and women in

Botswana, and follow-up has been completed. Participants were seen for monthly follow-up visits, and study drug was discontinued in women who became pregnant during the trial.

Among participants of both sexes combined, the efficacy of TDF/FTC was 62% (22%-83%). Efficacy estimates by sex did not statistically differ from each other or from the overall estimate, although the small number of endpoints in the subsets of men and women limited the statistical power to detect a difference. Compliance with study visits was low: 33.1% of participants did not complete the study per protocol. However, many were re-engaged for an exit visit, and 89.3% of enrolled participants had a final HIV test.

Among 3 participants later found to have been infected at enrollment, TDF/FTC-resistant virus was detected in 1 participant in the TDF/FTC group and a low level of TDF/FTC-resistant virus was transiently detected in 1 participant in the placebo group. No resistant virus was detected in the 33 participants who seroconverted after enrollment.

Medication adherence by pill count was 84% in both groups. Nausea, vomiting, and dizziness occurred more commonly, primarily during the first month of use, among those randomly assigned to TDF/FTC than among those assigned to placebo. The groups did not differ in rates of serious clinical or laboratory adverse events. Pregnancy rates and rates of fetal loss did not differ by study group.

FEM-PrEP Trial

The FEM-PrEP trial[30] was a phase 3 randomized, double-blind, placebo-controlled study of the HIV prevention efficacy and clinical safety of daily TDF/FTC among heterosexual women in South Africa, Kenya, and Tanzania. Participants were seen at monthly follow-up visits, and study drug was discontinued among women who became pregnant during the trial. The trial was stopped in 2011, when an interim analysis determined that the trial would be unlikely to detect a statistically significant difference in efficacy between the two study groups.

Adherence was low in this trial: study drug was detected in plasma samples of <50% of women randomly assigned to TDF/FTC. Among adverse events, only nausea and vomiting (in the first month) and transient, modest elevations in liver function test values were more common among those assigned to TDF/FTC than those assigned to placebo. No changes in renal function were seen in either group. Initial analyses of efficacy results showed 4.7 infections per 100/ person-years in the TDF/FTC group and 5.0 infections per 100 person-years in the placebo group. The hazard ratio 0.94 (95% CI, 0.59-1.52) indicated no reduction in HIV incidence associated with TDF/FTC use. Of the 68 women who acquired HIV infection during the trial, TDF or FTC resistant virus was detected in 5 women: 1 in the placebo group and 4 in the TDF/FTC group. In multivariate analyses, there was no association between pregnancy rate and study group.

Phase 2 Trial of Preexposure Prophylaxis with Tenofovir Among Women in Ghana, Cameroon, and Nigeria

A randomized, double-blind, placebo-controlled trial of oral tenofovir TDF was conducted among heterosexual women in West Africa - Ghana (n = 200), Cameroon (n = 200), and Nigeria (n = 136)[31]. The study was designed to assess the safety of TDF use and the efficacy of daily TDF in reducing the rate of HIV infection. The Cameroon and Nigeria study sites were closed prematurely because operational obstacles developed, so participant follow-up data were insufficient for the planned efficacy analysis. Analysis of trial safety data from Ghana and Cameroon found no statistically significant differences in grade 3 or 4 hepatic or renal events or in reports of clinical adverse events. Eight HIV seroconversions occurred among women in the trial: 2 among women in the TDF group (rate=0.86 per 100 person-years) and 6 among women receiving placebo (rate, 2.48 per 100 person-years), yielding a rate ratio of 0.35 (95% CI, 0.03-1.93; p=0.24). Blood specimens were available from 1 of the 2 participants who seroconverted while taking TDF; standard genotypic analysis revealed no evidence of drug-resistance mutations.

VOICE (Vaginal and Oral Interventions to Control the Epidemic) Trial

VOICE (MTN-003)[32] was a phase 2B randomized, double-blind study comparing oral (TDF or TDF/FTC) and topical vaginal (tenofovir) antiretroviral regimens against corresponding oral and topical placebos among 5,029 heterosexual women enrolled in eastern and southern Africa. Of these women, 3,019 were randomly assigned to daily oral medication (TDF/FTC, 1,003; TDF, 1,007; oral placebo, 1,009). In 2011, the trial group receiving oral TDF and the group receiving topical tenofovir were stopped after interim analyses determined futility. The group receiving oral TDF/FTC continued to the planned trial conclusion.

After the exclusion of 15 women later determined to have had acute HIV infection when enrolled in an oral medication group and 27 with no follow-up visit after baseline, 52 incident HIV infections occurred in the oral TDF group, 61 in the TDF/FTC group, and 60 in the oral placebo group. Effectiveness was not significant for either oral PrEP medication group; –49%% for TDF (hazard ratio [HR] 1.49; 95% CI, 0.97-2.29) and –4.4% for TDF/FTC (HR, 1.04; 95% CI, 0.73-1.49) in the modified-intent-to-treat analysis.

Face-to-face interview, audio computer-assisted self-interview, and pill-count medication adherence were high in all 3 groups (84%-91%). However, among 315 participants in the random cohort of the case-cohort subset for whom quarterly plasma samples were available, tenofovir was detected, on average, in 30% of samples from women randomly assigned to TDF and in 29% of samples from women randomly assigned to TDF/FTC. No drug was detected at any quarterly visit during study participation for 58% of women in the TDF group and 50% of women in the TDF/FTC group. The percentage of samples with detectable drug was less than 40% in all study drug groups and declined throughout the study. In a multivariate analysis that

adjusted for baseline confounding variables (including age, marital status), the detection of study drug was not associated with reduced risk of HIV acquisition.

The number of confirmed creatinine elevations (grade not specified) observed was higher in the oral TDF/FTC group than in the oral placebo group. However, there were no significant differences between active product and placebo groups for other safety outcomes. Of women determined after enrollment to have had acute HIV infection at baseline, two women from the TDF/FTC group had virus with the M184I/V mutation associated with FTC resistance. One woman in the TDF/FTC group who acquired HIV infection after enrollment had virus with the M184I/V mutation; No participants with HIV infection had virus with a mutation associated with tenofovir resistance.

In summary, although low adherence and operational issues precluded reliable conclusions regarding efficacy in 3 trials (VOICE, FEM-PrEP and the West African trial)[33], 2 trials (Partners PrEP and TDF2) with high medication adherence have provided substantial evidence of efficacy among heterosexual men and women. All 5 trials have found PrEP to be safe for these populations.

Daily oral PrEP with TDF/FTC is recommended as one HIV prevention option for heterosexually-active men and women at substantial risk of HIV acquisition because these trials present evidence of its safety and 2 present evidence of efficacy in these populations, especially when medication adherence is high. (IA).

Published Trial of Antiretroviral Preexposure Prophylaxis Among Persons Who Inject Drugs

Bangkok Tenofovir Study (BTS)

BTS[5] was a phase 3 randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF for HIV prevention among 2,413 PWID (also called IDU) in Bangkok, Thailand[5] The study was conducted at drug treatment clinics; 22% of participants were receiving methadone treatment at baseline. At each monthly visit, participants could choose to receive either a 28-day supply of pills or to receive medication daily by directly- observed therapy. Study clinics (n=17) provided condoms, bleach (for cleaning injection equipment), methadone, primary medical care, and social services free of charge. Participants were followed for 4.6 years (mean) and received directly- observed therapy 87% of the time.

In the modified intent- to-treat analysis (excluding 2 participants with evidence of HIV infection at enrollment), efficacy of TDF was 48.9% (95% CI, 9.6-72.2; P = .01). A post-hoc modified intent-to-treat analysis was done, removing 2 additional participants in whom HIV infection was identified within 28 days of enrollment, including only participants on directly observed therapy who met pre-established criteria for high adherence (taking a pill at least 71% of days and

missing no more than two consecutive doses), and had detectable levels of tenofovir in their blood. Among this set of participants, the efficacy of TDF in plasma was associated with a 73.5% reduction in the risk for HIV acquisition (95% CI, 16.6-94.0; $P = .03$). Among participants in an unmatched case-control study that included the 50 persons with incident HIV infection and 282 participants at 4 clinics who remained HIV uninfected, detection of TDF in plasma was associated with a 70.0% reduction in the risk for acquiring HIV infection (95% CI, 2.3-90.6; $P = .04$).

Rates of nausea and vomiting were higher among TDF than among placebo recipients in the first 2 months of medication but not thereafter. The rates of adverse events, deaths, or elevated creatinine did not differ significantly between the TDF and the placebo groups. Among the 49 HIV infections for which viral RNA could be amplified (of 50 incident infections and 2 infections later determined to have been present at enrollment), no virus with mutations associated with TDF resistance were identified.

Among participants with HIV infection followed up for a maximum of 24 months, HIV plasma viral load was lower in the TDF than in the placebo group at the visit when HIV infection was detected ($P = .01$), but not thereafter ($P = .10$).

Published Open-Label Study of Antiretroviral Preexposure Prophylaxis Among Person Who Inject Drugs

Bangkok Tenofovir Study (BTS) Open-Label Extension (OLE) Study

All 1315 participants in the randomized trial (BTS) who were HIV-negative and had no renal contraindication were offered daily oral TDF for 1 year in an open label extension study[34]. Sixty-one percent (n=798) elected to take PrEP. Participants who were older (≥30 years, $p<0.0001$), injected heroin ($p=0.007$) or had been in prison ($p=0.0007$) were more likely to start PrEP than those without these characteristics. Twenty-eight percent (n=220) did not return for any follow-up visits. Those who had injected heroin ($p=0.01$) or had been in prison ($p=0.0007$) during the 3 months before the open label study returned for a follow-up visit. Overall, by diary, adherence was lower in the open label study (38.5 % of days) than in the randomized clinical trial (83.8% of days). Those who injected midazolam ($p=0.02$) or were in prison ($p<0.0001$) during the open label study were more likely to be more than 90% adherent than those without these characteristics. During a median 335 days of follow-up, one HIV infection occurred in a participant who reported not taking any doses during the 60 days before the positive test, yielding an HIV incidence of 2.1 per 1000 py (95% CI: 0.05-11.7). Among the 339 (42%) who completed a 12-month follow-up visit, injection and needle sharing did not increase during the open-label study.

Daily oral PrEP with TDF/FTC (or TDF alone) is recommended as one HIV prevention option for PWID at substantial risk of HIV acquisition because this trial presents evidence of the safety and efficacy of TDF as PrEP in this population, especially when medication adherence is high. **(IA)**

Table 2: Evidence Summary — Overall Evidence Quality of Randomized Clinical Trials (per GRADE Criteria[35])

Study	Design[a]	Participants		Limitations	Quality of Evidence (See Table 14, Appendix 2)
		Agent	Control		
Among Men Who have Sex with Men					
iPrEx Trial	Phase 3	TDF/FTC (n = 1251)	Placebo (n = 1248)	Adherence	High
US MSM Safety Trial	Phase 2	TDF (n = 201)	Placebo (n = 199)	Minimal	High
ATN 082	Pilot	TDF/FTC (n=20)	Placebo (n=19) No pill (n=19)	Small size, stopped early, limited follow-up time, low medication adherence	Low
Among Heterosexual Men and Women					
Partners PrEP	Phase 3	TDF (n = 1589) TDF/FTC (n = 1583)	Placebo (n = 1586)	Minimal	High
TDF2	Phase 2	TDF/FTC (n = 611)	Placebo (n = 608)	High loss to follow-up; modest sample size	Moderate
Among Heterosexual Women					
FEM-PrEP	Phase 3	TDF/FTC (n = 1062)	Placebo (n = 1058)	Stopped at interim analysis, limited follow-up time; very low adherence to drug regimen	Low
West African Trial	Phase 2	TDF (n = 469)	Placebo (n = 467)	Stopped early for operational concerns; small sample size; limited follow-up time on assigned drug	Low
VOICE	Phase 2B	TDF (n = 1007) TDF/FTC (n = 1003)	Placebo (n = 1009)	TDF arm stopped at interim analysis (futility); very low adherence to drug regimen in both TDF and TDF/FTC arms	Low
Among Injection Drug Users					
BTS	Phase 3	TDF (n = 1204)	Placebo (n = 1207)	Minimal	High

Note: GRADE quality ratings:
high = further research is very unlikely to change our confidence in the estimate of effect:
moderate = further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate;
low = further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate;
very low = any estimate of effect is very uncertain.

[a] All trials in this table were randomized, double-blind, prospective clinical trials

Table 3: Evidence Summary of Randomized Clinical Trials — HIV Incidence Findings

Study	Outcome Analyses— HIV incidence (mITT)		Effect — HR [Efficacy Estimate] (95% CI)		
	Agent	Control			
iPrEx (MSM)	36 infections among 1224 persons	64 infections among 1217 persons	0.56 [44%] (0.37–0.85)		
US MSM Safety Trial	3 infections among 201 persons (all 3 in delayed arm, not on TDF)	4 infections among 199 persons (1 acute infection at enrollment)	Not Reported		
Partners PrEP (heterosexual men and women)	TDF 17 infections among 1572 persons TDF/FTC 13 infections among 1568 persons	52 infections among 1568 persons		TDF	TDF/FTC
			All	0.33 [67%] (0.19–0.56)	0.25 [75%] (0.13–0.45)
			Women	0.29 [71%] (0.13–0.63)	0.34 [66%] (0.16–0.72)
			Men	0.37 [63%] (0.17–0.80)	0.16 [84%] (0.06–0.46)
TDF2 (heterosexual men and women)	9 infections among 601 persons 1.2 infections/100 person-years	24 infections among 599 persons 3.1 infections per 100 person-years	0.38 [62%] (0.17–0.79)		
FEM-PrEP (heterosexual women)	33 infections among 1024 persons 4.7 infections per 100 person-years	35 infections among 1032 persons 5.0 infections per 100 person-years	0.94 [6%][a] (0.59–1.52)		
West African Trial (heterosexual women)	2 infections among 427 persons 0.86 infections per 100 person-years	6 infections among 432 persons 2.48 infections per 100 person-years	0.35 [65%][a] (0.03–1.93)		
VOICE (heterosexual women)	TDF 52 infections among 993 persons 6.3 infections per 100 person-years TDF/FTC 61 infections among 985 persons 4.7 infections per 100 person-years	35 infections among 999 persons 4.2 infections per 100 person-years	TDF	TDF/FTC	
			1.49 [-50 %][a] (0.97–2.3)	1.04 [-4%][a] (0.73, 1.5)	
BTS (persons who inject drugs)	17 infections among 1204 persons 0.35 infections per 100 person-years	33 infections among 1207 persons 0.68 infections per 100 person-years	0.51 [49%] (9.6, 72.2)		

mITT: modified intent to treat analysis; HR: hazard ratio.

[a] Not statistically significant.

Table 4: Measures of Efficacy, by Medication Adherence, Percentage Reduction in HIV Incidence in Randomized Clinical Trials (95% Confidence Interval)

Study	Modified Intent-to-Treat Efficacy			Efficacy by Self-report Adherence Measures	Efficacy by Pill-count Adherence Measures	Efficacy by Blood Detection of Drug Measures[a]
iPrEx (TDF/FTC)	44% (15–63%)			>50% 50% (18–70%) >90% 73% (41–88%)		92% (40–99%)
Partners PrEP	All TDF: 67% TDF/FTC: 75%	Men TDF: 63% TDF/FTC: 84%	Women TDF: 71% TDF/FTC: 66%	NR	100% (87–100%)	TDF: 86% (67–94%) TDF/FTC: 90% (58–98%)
TDF2 (TDF/FTC)	All 63%	Men 80%	Women 49%[b]	NR	NR	TDF detected: 85%[b]
FEM-PrEP (TDF/FTC)	NR			NR	NR	NR
VOICE (TDF,TDF/FTC)	NR			NR	NR	NR
BTS (TDF)	49%			NR	56% (-19 to 86%)[c]	74% (17–94%)

NR, not reported.

[a] Tenofovir detection assays were done in subsets of persons randomly assigned to receive TDF or TDF/FTC

[b] Finding not statistically significant

[c] Among participants on directly observed therapy

3143

Table 5: Evidence Summary of Randomized Clinical Trials — Safety and Toxicity

Study	Outcome Analyses	
	Agent	Control
Grade 3/4 Adverse Clinical Events[a]		
iPrEx	52 events	59 events
ATN 082	1 event	1 event
TDF2	9 events	10 events
West African Trial	NR	NR
Grade 3/4 Adverse Laboratory Events [a]		
iPrEx	59 events	48 events
ATN 082	3 events	0 events
TDF2	32 events	32 events
West African Trial	1 event	5 events
Grade 3/4 Adverse Events (Clinical and Laboratory)[a]		
Partners PrEP	TDF: 323 events TDF/FTC: 337 events	307 events
FEM-PrEP	NR	NR
US MSM Safety Trial	36 events	26 events
VOICE	NR	NR
BTS	175 events	173 events

NR, not reported.

[a] RDBPCT = randomized, double-blind, prospective clinical trial

3144

Table 6: Evidence Summary of Randomized Clinical Trials — HIV Resistance Findings (TDF or FTC Drug Resistant Virus Detected)

Study	Outcome Analyses	
	Agent	Control
iPrEx	2 resistant viruses among 2 persons infected at baseline 0 resistant viruses among 36 persons infected after baseline	1 resistant virus among 8 persons infected at baseline 0 resistant viruses among 64 persons infected after baseline
US MSM Safety Trial	0 resistant viruses among 3 persons infected after baseline (in delayed arm before starting drug)	1 resistant virus among 1 person infected at baseline 0 resistant viruses among 3 persons infected after baseline
Partners PrEP	2 resistant viruses among 5 persons infected at baseline and randomly assigned to TDF 1 resistant virus among 3 persons infected at baseline and randomly assigned to TDF/FTC 0 resistant viruses among 27 persons infected after baseline	0 resistant viruses among 6 persons infected at baseline 0 resistant viruses among 51 persons infected after baseline
TDF2	1 resistant virus in 1 person infected at baseline 0 resistant viruses among 9 persons infected after baseline	1 resistant virus in 1 person infected at baseline (very low frequency and transient detection) 0 resistant viruses among 24 persons infected after baseline
FEM-PrEP	4 resistant viruses among 33 persons infected after baseline	1 resistant virus in 35 persons infected after baseline
West African Trial	0 resistant viruses among 2 persons infected while on TDF	NR
VOICE	NR	—
BTS	0 resistant viruses among 49 persons infected after baseline	

NR, not reported.

3145

Table 7. Evidence Summary of Open-Label Studies (daily oral TDF/FTC)

Study	Design	Population	Effect HR [Efficacy Estimate]	Efficacy by Blood Detection of Drug Measure	Resistance
PROUD	Wait-list Control	MSM	[86%] [90% CI: 64%-96%] comparing immediate vs. deferred group	Not reported	• 2 resistant viruses among 3 persons infected at baseline • 0 resistant viruses among 23 persons infected after baseline
iPrEx OLE[a]	RCT Open-Label Extension	MSM	0.51 [49%] (95% CI: 0.26-1.01) comparing those electing to use PrEP with those who did not , adjusted for baseline sexual risk behavior	Compared with being off PrEP, HRs for seroconversion stratified by weekly dosing inferred from blood drug levels: <2 doses/week 0.56 [44%](0.23-1.31) 2-3 doses/week 0.16 [84%] (0.01-0.79) 4-6 doses/week 0.0 [100%] (0.0-0.21) 7 doses/week 0.0 [100%] (0.0-0.43)	• 0 resistant viruses among 2 persons infected at baseline (not started on PrEP) • 1 resistant virus among 28 persons infected after baseline started on PrEP • 0 resistant viruses among 13 persons infected after baseline not started on PrEP
Demo Project	Clinical Cohort	MSM[b]	HIV incidence 0.43 per 100 py (no comparison group) in a population with an STI incidence of 90 per 100 py observed during follow-up.[b]	Both seroconverters had blood drug levels associated with <2 doses/week	• 1 resistant virus among 3 persons infected at enrollment and started on PrEP • 0 resistant viruses among 2 persons infected after baseline started on PrEP
Kaiser Permanente	Clinical Cohort	MSM	0 HIV diagnoses in 5104 py of follow-up	Not reported	Not applicable

[a] included men who had participated in the iPrEx, CDC Safety, and Adolescent Trials Network 082 PrEP trials
[b] 653 MSM, 3 heterosexual women, 1 transgender man who has sex with men

Identifying Indications for PrEP

Taking a sexual history is recommended for all adult and adolescent patients as part of ongoing primary care, but the sexual history is often deferred because of urgent care issues, provider discomfort, or anticipated patient discomfort. This deferral is common among providers of primary care[36], STI care[37], and HIV care[38-40].

Routinely taking a sexual history is a necessary first step to identify which patients in a clinical practice are having sex with same-sex partners, which are having sex with opposite-sex partners, and what specific sexual behaviors may place them at risk for, or protect them from, HIV acquisition. To identify the sexual health needs of all their patients, clinicians should not limit sexual history assessments to only selected patients (e.g., young, unmarried persons or women seeking contraception), because new HIV infections and STIs are occurring in all adult and adolescent age groups, both sexes, and both married and unmarried persons. The clinician can introduce this topic by stating that taking a brief sexual history is routine practice, go on to explain that the information is necessary to the provision of individually appropriate sexual health care, and close by reaffirming the confidentiality of patient information.

Transgender persons are those whose sex at birth differs from their self-identified gender. Although the effectiveness of PrEP for transgender women has not yet been definitively proven in trials[19], and trials have not been conducted among transgender men, PrEP has been shown to reduce the risk for HIV acquisition during anal sex and penile-vaginal sex. Therefore, its use may be considered in all persons at risk of acquiring HIV sexually.

Assessing Risk of Sexual HIV Acquisition

Because offering PrEP is currently indicated for MSM at substantial risk of HIV acquisition, it is important to consider that although 76% of MSM surveyed in 2008 in 21 US cities reported a health care visit during the past year[41], other studies reported that health care providers do not ask about, and patients often do not disclose, same-sex behaviors[42]. Box A1 contains a set of brief questions designed to identify men who are currently having sex with men and to assess a key set of sexual practices that are associated with the risk of HIV acquisition. In studies to develop scored risk indexes predictive of incident HIV infection among MSM[43,44] (see Clinical Providers' Supplement, Section 6), several critical factors were identified.

Box A1: Risk Behavior Assessment for MSM[44]

In the past 6 months:

- Have you had sex with men, women, or both?
- *(if men or both sexes)* How many men have you had sex with?
- How many times did you have receptive anal sex (you were the bottom) with a man who was not wearing a condom?
- How many of your male sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive male partners, how many times did you have insertive anal sex (you were the top) without you wearing a condom?
- Have you used methamphetamines (such as crystal or speed)?

Box A2 contains a set of brief questions designed to identify women and men who are currently having sex with opposite-sex partners (heterosexually active) and to assess a key set of sexual practices that are associated with the risk of HIV acquisition as identified both in PrEP trials and epidemiologic studies[45-48].

Box A2: Risk Behavior Assessment for Heterosexual Men and Women

In the past 6 months:

- Have you had sex with men, women, or both?
- *(if opposite sex or both sexes)* How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?

In addition, for all sexually active patients, clinicians may want to consider reports of diagnoses of bacterial STIs (chlamydia, syphilis, gonorrhea) during the past 6 months as evidence of sexual activity that could result in HIV exposure. For heterosexual women and men, sex without a condom (or its correct use) may also be indicated by recent pregnancy of a female patient or sexual partner of a male patient.

Clinicians should also briefly screen all patients for alcohol abuse[49] (especially before sexual activity) and the use of illicit non-injection drugs (e.g., amyl nitrite, stimulants) [50,51]. The use of these substances may affect sexual risk behavior[52], hepatic or renal health, or medication adherence, any of which may affect decisions about the appropriateness of prescribing PrEP medication. In addition, if substance abuse is reported, the clinician should provide referral for appropriate treatment or harm-reduction services acceptable to the patient.

Lastly, clinicians should consider the epidemiologic context of the sexual practices reported by the patient. The risk of HIV acquisition is determined by both the frequency of specific sexual practices

(e.g., unprotected anal intercourse) and the likelihood that a sex partner has HIV infection. The same behaviors when reported as occurring in communities and demographic populations with high HIV prevalence or occurring with partners known to have HIV infection, are more likely to result in exposure to HIV and so will indicate greater need for intensive risk-reduction methods (PrEP, multisession behavioral counseling) than when they occur in a community or population with low HIV prevalence (see http://www.AIDSvu.org or http://www.cdc.gov/nchhstp/atlas/).

After assessing the risk of HIV acquisition, clinicians should discuss with the patient which of several effective prevention methods (e.g., PrEP, behavioral interventions) will be pursued (see CDC HIV risk reduction tool at https://wwwn.cdc.gov/hivrisk/estimator.html#). When supporting consistent and correct condom use is feasible and the patient is motivated to achieve it, high levels of protection against both HIV and several STIs[48] are afforded without the side effects or cost of medication. A clinician can support consistent condom use by providing brief clinical counseling (see Clinical Providers' Supplement, Section 11), by referring the patient to behavioral medicine or health education staff in the clinical setting, or by referring the patient to community-based or local health department counseling and support services.

Reported consistent ("always") condom use is associated with an 80% reduction in HIV acquisition among heterosexual couples[53] and 70% among MSM[57]. However, inconsistent condom use is less effective[45,55], and studies have reported low rates of recent consistent condom use among MSM[57,59] and other sexually active adults[57]. Especially low rates have been reported when condom use was measured over several months rather than during most recent sex or the past 30 days[58]. Therefore, unless the patient reports confidence that consistent condom use can be achieved, additional HIV prevention methods, including the consideration of PrEP should be provided while continuing to support condom.

A patient who reports that 1 or more regular sex partners is of unknown HIV status should be offered HIV testing for those partners, either in the clinician's practice or at a confidential testing site (see zip code lookup at http://www.hivtest.org/).

Lastly, for any regular sex partner reported to be HIV-positive, clinician should determine whether the HIV-negative patient knows if the HIV-positive partner is receiving antiretroviral therapy and whether a recent evaluation indicates an undetectable viral load. In addition to the known health benefits of viral load suppression by antiretroviral therapy, a recent clinical trial (HPTN 052[59]) demonstrated that antiretroviral therapy also substantially protects against HIV transmission to a heterosexual partner. Among 1,753 HIV discordant couples where the infected partner was treated, transmission risk was reduced 93%. All documented infections where viral genetic linkage was confirmed occurred in the context of an unsuppressed viral load in the partner initially infected with HIV. Another study included 548 HET and 340 MSM HIV-discordant couples where the partner with HIV infection was virally suppressed with antiretroviral treatment[60,61]. This study observed no HIV transmissions to the uninfected partner despite approximately 58,000 reported episodes of condomless vaginal or anal intercourse during 1,200 couple/years of observation substantial protection (100%). However, some persons who know they have HIV infection may not be in care, may not be receiving antiretroviral

therapy, may not be receiving highly effective regimens, may not be adherent to their medications, or for other reasons may not have viral loads that are associated with the least risk of transmission to an uninfected sex partner[62,63]. In addition, clinicians providing care to the HIV-negative patient may not have access to the medical records of the HIV-positive partner to document their recent viral load status and over time.

Box B1: Recommended Indications for PrEP Use by MSM[2]

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Box B2: Recommended Indications for PrEP Use by Heterosexually Active Men and Women

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

Assessing Risk of HIV Acquisition Through Injection Practices

Although the annual number of new HIV infections among PWID in the United States has declined, a sizable number occur each year. In 2010, PWID accounted for 8% of estimated incident HIV infections[13]. According to the National HIV Behavioral Surveillance System (NHBS)[64] substantial proportions of PWID report sharing syringes (34%) and sharing injection equipment (58%). In addition, in NHBS and epidemiologic studies conducted with PWID, most PWID report sexual behaviors that also confer risk of HIV acquisition[65]. Because of the efficacy and safety demonstrated in the PrEP trial with PWID, providing PrEP to those who report injection behaviors that place them at substantial risk of acquiring HIV infection could contribute to HIV prevention for PWID at both the individual and the population level.

Although current evidence is insufficient for a recommendation that all patients be screened for injection or other illicit drug use, the US Preventive Services Task Force recommends that clinicians be alert to the signs and symptoms of illicit drug use in patients[66]. Clinicians should determine whether patients who are currently using illicit drugs are in (or want to enter) behavioral, medication-assisted, or in-patient drug treatment. For persons with a history of injecting illicit drugs but who are currently not injecting, clinicians should assess the risk of relapse along with the patients' use of relapse prevention services (e.g., a drug-related behavioral support program, use of mental health services, 12-step program).

Box A3 contains a set of brief questions that may help identify persons who are injecting illicit drugs, and to assess a key set of injection practices that are associated with the risk of HIV acquisition as identified in the PrEP trial with PWID[5] and in epidemiologic studies[64,67] (for a scored risk index predictive of incident HIV infection among PWID[63], see the Clinical Providers' Supplement, Section 7)

Box A3: Risk Behavior Assessment for Persons Who Inject Drugs[68]

- Have you ever injected drugs that were not prescribed to you by a clinician?
- *(if yes)*, When did you last inject unprescribed drugs?
- In the past 6 months, have you injected by using needles, syringes, or other drug preparation equipment that had already been used by another person?
- In the past 6 months, have you been in a methadone or other medication-based drug treatment program?

Box B3: Recommended Indications for PrEP Use by Persons Who Inject Drugs

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

PrEP or other HIV prevention should be integrated with prevention and clinical care services for the many health threats PWID may face (e.g., hepatitis B and C infection, abscesses, septicemia, endocarditis, overdose)[69] In addition, referrals for drug treatment, mental health services, and social services may be indicated.

Laboratory Tests and Other Diagnostic Procedures

All patients whose sexual or drug injection history indicates consideration of PrEP and who are interested in taking PrEP must undergo laboratory testing to identify those for whom this intervention would be harmful or for whom it would present specific health risks that would require close monitoring.

HIV testing

HIV testing and the documentation of results are required to confirm that patients do not have HIV infection when they start taking PrEP medications. For patient safety, HIV testing and should be repeated at least every 3 months (before prescriptions are refilled or reissued). This requirement should be explained to patients during the discussion about whether PrEP is appropriate for them.

The Centers for Disease Control and Prevention (CDC) and the US Preventive Services Task Force recommends that MSM, PWID, patients with a sex partner who has HIV infection, and others at substantial risk of HIV acquisition undergo an HIV test at least annually or for those with additional risk factors, every 3-6 months[70,71]. However, outside the context of PrEP delivery, testing is often not done as frequently as recommended[72].

Clinicians should document a negative antibody test result within the week before initiating (or reinitiating) PrEP medications, ideally with an antigen/antibody test conducted by a laboratory. The required HIV testing can be accomplished by (1) drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test or and antibody-only test or (2) performing a rapid, point-of-care, FDA-approved, fingerstick blood test. Rapid tests that use oral fluid should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests[73]. Clinicians should not accept patient-reported test results or documented anonymous test results. A

preliminary positive HIV antibody test must be confirmed according to the local laboratory standard practice[74] and viral load and CD4 lymphocyte tests should be ordered to assist in future treatment decisions.

See http://www.cdc.gov/hiv/testing/laboratorytests.html for FDA-approved HIV tests, specimen requirements, and time to detection of HIV infection.

Acute HIV Infection

In the iPrEx trial, drug-resistant virus developed in 2 persons with unrecognized acute HIV infection at enrollment and for whom TDF/FTC had been dispensed. These participants had negative antibody test results before they started taking PrEP, tested positive at a later study visit, and PCR (polymerase chain reaction) on stored specimens from the initial visit detected the presence of virus. When questioned, most of the 10 acutely infected participants (8 of whom had been randomly assigned the placebo group) reported signs and symptoms consistent with a viral syndrome[2]. Both acutely infected patients to whom TDF/FTC had been dispensed had the M184V/I mutation associated with emtricitabine resistance, but not the K65R mutation associated with tenofovir resistance[2]. Among participants who were dispensed PrEP medication in the US MSM Safety Trial and in the Partners PrEP, TDF2, and VOICE trials (see Table 6), the M184V mutation, developed in several persons who were enrolled and had started taking medication with unrecognized acute HIV infection but K65R developed in only one (in the TDF2 study). However, no mutations emerged in persons who acquired infection after baseline. In the one trial with very low medication adherence that has published its resistance testing results, the emtricitabine resistance mutation, but not the K65R mutation was found in a few persons with incident infection after baseline (4 persons in the FEM-PrEP trial).

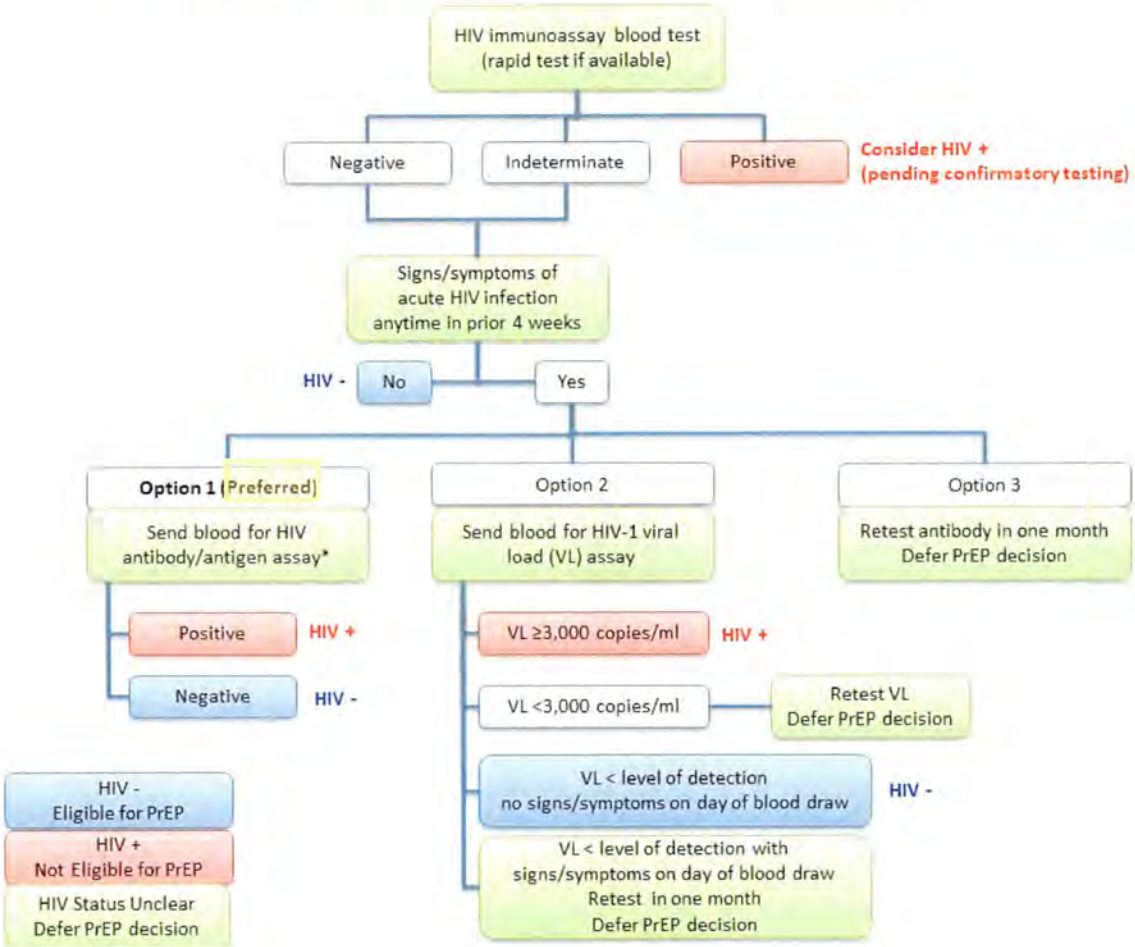
PrEP is indicated for MSM, heterosexual men and women, and PWID who report injection or sexual behaviors that place them at substantial risk of HIV acquisition. Therefore clinicians should suspect acute HIV infection in persons known to have been exposed recently (e.g., a condom broke during sex with an HIV-infected partner, relapse to injection drug use with shared injection equipment). In addition, clinicians should solicit a history of nonspecific signs or symptoms of viral infection during the preceding month or on the day of evaluation (see Table 8) in all PrEP candidates with a negative or an indeterminate result on an HIV antigen/antibody or antibody-only test.

Table 8: Clinical Signs and Symptoms of Acute (Primary) HIV Infection[75]

Features	Overall (n = 375) %	Sex		Route of transmission	
		Male (n = 355) %	Female (n = 23) %	Sexual (n = 324) %	Injection Drug Use (n = 34) %
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

The figure below illustrates the recommended clinical testing algorithm to establish HIV infection status before the initiation of PrEP or its re-initiation after more than a week off PrEP medication. . Laboratory antigen/antibody tests (option 1) are preferred because they have the highest sensitivity for detecting acute HIV infection which is associated with high viral loads. While viral load testing is sensitive (option 2), healthcare providers should be aware that available assays might yield false-positive low viral load results (e.g., <3,000 copies/mL) among persons without HIV infection. Without confirmatory tests, such false-positive results can lead to misdiagnosis of HIV infection.[76,77] Repeat antibody testing (option 3) is least preferred because it delays determination of true HIV status and uninfected patients may have additional exposures and become infected without PrEP while waiting to retest. When clinicians prescribe PrEP based solely on the results of antibody-only or rapid tests, ordering a laboratory antigen/antibody test at the time baseline labs are drawn is recommended. This will increase the likelihood of detecting unrecognized acute infection so that PrEP can be stopped and the patient started on antiretroviral treatment in a timely manner.

Figure Clinician Determination of HIV Status for PrEP Provision



RENAL FUNCTION

In addition to confirming that any person starting PrEP medication is not infected with HIV, a clinician should determine renal function and test for infection with hepatitis B virus (HBV) because both decreased renal function and active HBV infection are potential safety issues for the use of TDF/FTC as PrEP.

TDF is widely used in combination antiretroviral regimens for the treatment of HIV infection[78]. Among HIV-infected persons prescribed TDF-containing regimens, decreases in renal function (as measured by estimated creatinine clearance [eCrCl]) have been documented, and occasional cases of acute renal failure, including Fanconi's syndrome, have occurred [79-81].

In the PrEP trials among otherwise healthy, HIV-uninfected adults, an eCrCl of ≥60 ml/min was an eligibility criterion. Safety data for TDF/FTC prescribed to persons with reduced renal function are not available. Therefore, for all persons considered for PrEP, a serum creatinine test should be done, and

an eCrCL should be calculated by using the Cockcroft-Gault formula (see Box C). Any person with an eCrCl of <60 ml/min should not be prescribed PrEP with TDF/FTC.

Box C Cockcroft-Gault Formulas

Basic Formula[82]

$eCrCl_{CG}$ = [[(140 - age) × IBW × 0.85 for females] ÷ (serum creatinine × 72)]

IBW = ideal body weight Males: IBW = 50 kg + 2.3 kg for each inch over 5 feet
Females: IBW = 45.5 kg + 2.3 kg for each inch over 5 feet

Age in years, weight in kg, and serum creatinine in mg/100mL

Optional adjustment for low actual body weight[83]
If the actual body weight is less than the IBW (ideal body weight) use the actual body weight for calculating the eCrCl.

Optional adjustment of high actual body weight[83]
Used only if the actual body weight is 30% greater than the IBW. Otherwise, the IBW is used.

eCrCl = [[(140 - age) × AjBW] ÷ (serum creatinine × 72)] (× 0.85 for females)

AjBW = IBW + 0.3(ABW - IBW)
AjBW = adjusted body weight ABW = actual body weight

Optional adjustment for body surface area (BSA)[84]
Can be used if actual body weight is greater or less than IBW

$eCrCl_{BSAadj}$ = 1.73m^2 × $eCrCl_{CG}$ (ml/min) ÷ BSA of the patient (m^2)

BSA (DuBois and DuBois formula[74]) = (height (m)$^{0.725}$ × weight (kg)$^{0.425}$) ÷ 139.2

Hepatitis Serology

Sexually active adults (especially MSM), and persons who inject illicit drugs, are at risk of acquiring HBV infection[85] and hepatitis C virus (HCV) infection[86].

Vaccination against HBV is recommended for all adolescents and adults at substantial risk for HIV infection, especially for MSM. Therefore, HBV infection status should be documented by screening serology before TDF/FTC is prescribed as PrEP (see Table 9). Those patients determined to be susceptible to HBV infection should be vaccinated. Those patients found to be HBsAg positive should

be evaluated for possible treatment either by the clinician providing PrEP care or by linkage to an experienced HBV care provider.

HBV infection is not a contraindication to PrEP use. Both TDF and FTC are active against HBV[87]. HBV-monoinfected patients taking TDF or FTC, whether as PrEP or to treat HBV infection, who then stop these medications must have their liver function closely monitored for reactivation of HBV replication that can result in hepatic damage[6].

Table 9: Hepatitis B Screening Serology

HBsAg	Total anti-HBc	IgM anti-HBc	anti-HBs	Interpretation	Action
Negative	Negative	—	Negative	Susceptible	Vaccinate
Negative	Positive	—	Positive*	Immune (natural infection)	Document
Negative	Negative	—	Positive*	Immune (prior vaccination)	Document
Positive	Positive	Negative	Negative	Chronic HBV infection	Evaluate for treatment
Positive	Positive	Positive	Negative	Acute HBV infection	Follow and evaluate for treatment
Negative	Positive	—	Negative	Unclear—could be: • Resolved infection (most common) • False-positive anti-HBc; susceptible • "low level" chronic infection • Resolving acute infection	Case-by-case evaluation

*= seroprotective levels of >10 mIU/mL

For additional guidance about the management of PrEP in persons with chronic active HBV infection see the section Special Clinical Considerations.

Serologic testing for HCV is recommended for persons who have ever injected drugs[88]. MSM at substantial risk for HIV infection being started on PrEP have been shown to have a high prevalence of HCV infection [89,90,91]. Therefore, MSM starting PrEP should be tested for HCV infection as a part of baseline laboratory assessment. HCV testing for all sexually active persons starting PrEP is a recommended consideration by guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA)[92]. In addition, persons born during 1945 through 1965 should be tested for HCV at least once in a lifetime (without prior ascertainment of HCV risk factors). Guidance from AASLD-IDSA recommends annual HCV retesting

for PWID, and clinicians can consider annual retesting for other persons with ongoing risk of HCV exposure[92].

Patients with active HCV infection (HCV RNA+ with or without anti-HCV seropositivity) should be evaluated for possible treatment because TDF/FTC does not treat HCV infection. When the clinician providing PrEP care is not able to provide HCV care, the patient should be linked to an experienced HCV care provider

Testing for Sexually transmitted Infections

Tests to screen for syphilis are recommended for all adults prescribed PrEP, both at screening and at semi-annual visits. See the 2015 STD guidelines for recommended assays[93].

Tests to screen for gonorrhea are recommended for all sexually active adults prescribed PrEP, both at screening and at semi-annual visits. Tests to screen for chlamydia are recommended for all sexually active MSM prescribed PrEP, both at screening prior to initiation and at semi-annual visits.

Because chlamydia is very common, especially in young women[94] and does not strongly correlate with risk of HIV acquisition[61], regular screening for chlamydia is not recommended for all sexually active women as a component of PrEP care. However, clinicians should refer to the 2015 STD guidelines for recommendations about chlamydia testing frequency for women regardless of PrEP use[93].

For gonorrhea and chlamydia testing in MSM, NAAT tests are preferred because of their sensitivity. Pharyngeal, rectal, and urine specimens should be collected ("3-site testing") to maximize the identification of infection, which may occur at any of these sites of exposure during sex. Self-collected samples have equivalent performance as clinician-obtained samples [95-97] and can help streamline patient visit flow.

For gonorrhea testing in women, vaginal specimens for NAAT tests are preferred. They may also be self-collected. For women who report engaging in anal sex, rectal specimens for gonorrhea and chlamydia testing should be collected in addition to vaginal specimens[98-100]. Studies have estimated that 29% of HIV infections in women are linked to sex with MSM (i.e., bisexual men)[101,102], and that more than 1/3 of women report having had anal sex[103]. In the HPTN 064 trial that recruited women at high risk of HIV acquisition, 38% reported condomless anal sex in the 6 months prior to enrollment[104]. Identifying asymptomatic rectal gonorrhea in women at substantial risk for HIV infection and providing treatment can provide benefits to the woman's health and help reduce the burden of infection in her sexual networks as well[105,106], especially when accompanied by partner services[107] or expedited partner therapy[108-110].

Providing PrEP

Goals of PrEP Therapy

The ultimate goal of PrEP is to reduce the acquisition of HIV infection with its resulting morbidity, mortality, and cost to individuals and society. Therefore clinicians initiating the provision of PrEP should

- Prescribe medication regimens that are proven safe and effective for uninfected persons who meet recommended criteria to reduce their risk of HIV acquisition
- Educate patients about the medications and the regimen to maximize their safe use
- Provide support for medication-adherence to help patients achieve and maintain protective levels of medication in their bodies
- Provide HIV risk-reduction support and prevention services or service referrals to help patients minimize their exposure to HIV
- Provide effective contraception to women who are taking PrEP and who do not wish to become pregnant
- Monitor patients to detect HIV infection, medication toxicities, and levels of risk behavior in order to make indicated changes in strategies to support patients' long-term health

Indicated Medication

The medication proven safe and effective, and currently approved by FDA for PrEP in healthy adults at risk of acquiring HIV infection, is the fixed-dose combination of TDF and FTC in a single daily dose (see Table 10). Therefore, TDF/FTC is the recommended medication that should be prescribed for PrEP for MSM, heterosexually active men and women, and PWID who meet recommended criteria. Because TDF alone has been proven effective in trials with PWID and heterosexually active men and women, it can be considered as an alternative regimen for these specific populations. As PrEP for MSM, TDF alone is not recommended because no trials have been done, so the efficacy of TDF alone for MSM is unknown.

Table 10: Recommended Oral PrEP Medications

Generic Name	Trade Name	Dose	Frequency	Common Side Effects[73]
Tenofovir disoproxil fumarate (TDF)	Viread	300 mg	Once a day	Nausea, flatulence
Emtricitabine (FTC)[a]	Emtriva	200 mg	Once a day	Rash, headache
TDF + FTC	Truvada	300mg/200 mg	Once a day	—

[a] Not recommended alone; only for use in combination with TDF.

In addition to the safety data obtained in PrEP clinical trials, data on drug interactions and longer-term toxicities have been obtained by studying the component drugs individually for their use in treatment of HIV-infected persons. Studies have also been done in small numbers of HIV-uninfected, healthy adults (see Table 11).

Table 11: PrEP Medication Drug Interactions [6,80]

	TDF	FTC
Buprenorphine	No significant effect. No dosage adjustment necessary.	No data
Methadone	No significant effect. No dosage adjustment necessary.	No data
Oral contraceptives	No significant effect. No dosage adjustment necessary.	No data
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion	Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities.	No data
Ledipasvir/sofosbuvir	Serum concentrations of TDF may be increased. Monitor for toxicities.	No significant effect

WHAT NOT TO USE

No antiretroviral regimens should be used for PrEP other than a daily oral dose of TDF/FTC, or a daily dose of TDF alone as an alternative only for PWID and heterosexually active adults.

Other medications and other dosing schedules have not yet been shown to be safe or effective in preventing HIV acquisition among otherwise healthy adults and are not approved by FDA for PrEP.

- Do not use other antiretroviral medications (e.g., 3TC, TAF [tenofovir alafenamide]), either in place of, or in addition to, TDF/FTC or TDF.
- Do not use other than daily dosing (e.g., intermittent, episodic [pre/post sex only], or other discontinuous dosing)
- Do not provide PrEP as expedited partner therapy (i.e., do not prescribe for an uninfected person not in your care).

TIME TO ACHIEVING PROTECTION

The time from initiation of daily oral doses of TDF/FTC to maximal protection against HIV infection is unknown. There is not scientific consensus on what intracellular concentrations are protective for either drug or the protective contribution of each drug in specific body tissues. It has been shown that the pharmacokinetics of TDF and FTC vary by tissue[111].

Data from exploratory pharmacokinetic studies conducted with HIV-uninfected men and women does provide preliminary data on the lead-time required to achieve steady state levels of tenofovir diphosphate (TFV-DP, the activated form of the medication) in blood (PBMCs [peripheral blood mononuclear cells]), rectal, and vaginal tissues[112,113]. These data suggest that maximum intracellular

concentrations of TFV-DP are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at approximately 20 days. No data are yet available about intracellular drug concentrations in penile tissues susceptible to HIV infection to inform considerations of protection for male insertive sex partners.

MANAGING SIDE EFFECTS

Patients taking PrEP should be informed of side effects among HIV-uninfected participants in clinical trials (see Table 5). In these trials, side effects were uncommon and usually resolved within the first month of taking PrEP ("start-up syndrome"). Clinicians should discuss the use of over-the-counter medications for headache, nausea, and flatulence should they occur. Patients should also be counseled about signs or symptoms that indicate a need for urgent evaluation (e.g., those suggesting possible acute renal injury or acute HIV infection).

CLINICAL FOLLOW-UP AND MONITORING

Once PrEP is initiated, patients should return for follow-up approximately every 3 months. Clinicians may wish to see patients more frequently at the beginning of PrEP (e.g., 1 month after initiation, to assess and confirm HIV-negative test status, assess for early side effects, discuss any difficulties with medication adherence, and answer questions.

All patients receiving PrEP should be seen as follows:

- **At least every 3 months to**
  - Repeat HIV testing and assess for signs or symptoms of acute infection to document that patients are still HIV negative (see Figure)
  - Repeat pregnancy testing for women who may become pregnant
  - Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test)
  - Assess side effects, adherence, and HIV acquisition risk behaviors
  - Provide support for medication adherence and risk-reduction behaviors
  - Respond to new questions and provide any new information about PrEP use
  - Conduct STI testing for sexually active persons with signs or symptoms of infection and screening for asymptomatic MSM at high risk for recurrent bacterial STIs (e.g., those with syphilis, gonorrhea, or chlamydia at prior visits or multiple sex partners)
- **At least every 6 months to**
  - Monitor eCrCl
    - If other threats to renal safety are present (e.g., hypertension, diabetes), renal function may require more frequent monitoring or may need to include additional tests (e.g., urinalysis for proteinuria)
    - A rise in serum creatinine is not a reason to withhold treatment if eCrCl remains ≥60 ml/min.

- If eCrCl is declining steadily (but still ≥60 ml/min), consultation with a nephrologist or other evaluation of possible threats to renal health may be indicated.

- Conduct STI screening for sexually active adolescents and adults (i.e., syphilis and gonorrhea for both men and women, chlamydia for MSM) even if asymptomatic

- **At least every 12 months to**
  - Evaluate the need to continue PrEP as a component of HIV prevention

Optional Assessments

Bone Health

Decreases in bone mineral density (BMD) have been observed in HIV-infected persons treated with combination antiretroviral therapy (including TDF-containing regimes)[114,115]. However, it is unclear whether this 3%-4% decline would be seen in HIV-uninfected persons taking fewer antiretroviral medications for PrEP. The iPrEx trial (TDF/FTC) and the CDC PrEP safety trial in MSM (TDF) conducted serial dual-emission x-ray absorptiometry (DEXA) scans on a subset of MSM in the trials and determined that a small (~1%) decline in BMD that occurred during the first few months of PrEP either stabilized or returned to normal[23,116]. There was no increase in fragility (atraumatic) fractures over the 1-2 years of observation in these studies comparing those persons randomized to receive PrEP medication and those randomized to receive placebo[117].

Therefore, DEXA scans or other assessments of bone health are not recommended before the initiation of PrEP or for the monitoring of persons while taking PrEP. However, any person being considered for PrEP who has a history of pathologic or fragility bone fractures or who has significant risk factors for osteoporosis should be referred for appropriate consultation and management.

Therapeutic Drug Monitoring

Similar to the limited use of therapeutic drug monitoring (TDM) in the treatment of HIV infection[80], several factors mitigate against the routine use of TDM during PrEP. These factors include (1) a lack of established concentrations in blood associated with robust efficacy of TDF or FTC for the prevention of HIV acquisition in adults after exposure during penile-rectal or penile-vaginal intercourse[118] and (2) the limited but growing availability of clinical laboratories that perform quantitation of antiretroviral medicine concentrations under rigorous quality assurance and quality control standards.

However, some clinicians may want to use TDM periodically to assess adherence to PrEP medication. If so, a key limitation should be recognized. The levels of medication in serum or plasma reflect only very recent doses, so they are not valid estimates of consistent adherence[118]. However, if medication is not detected or is detected at a very low level, support to reinforce medication adherence would be indicated.

Persons with Documented HIV Infection

All persons with HIV-positive test results whether at screening or while taking TDF/FTC or TDF alone as PrEP should be provided the following services[80].

- Laboratory confirmation of HIV status (see Figure)
- Determination of CD4 lymphocyte count and viral load to guide therapeutic decisions
- Documentation of results of genotypic HIV viral resistance testing to guide future treatment decisions
- If on PrEP, conversion of the PrEP regimen to an HIV treatment regimen recommended by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents[80] without waiting for additional laboratory test results. See Clinical Providers' Supplement Section 8.
- Provision of, or referral to, an experienced provider for the ongoing medical management of HIV infection
- Counseling about their HIV status and steps they should take to prevent HIV transmission to others and to improve their own health
- Assistance with, or referral to, the local health department for the identification of sex partners who may have been recently exposed to HIV so that they can be tested for HIV infection, considered for nonoccupational postexposure prophylaxis (nPEP)[119], and counseled about their risk-reduction practices

In addition, a confidential report of new HIV infection should be provided to the local health department.

Discontinuing PrEP

Patients may discontinue PrEP medication for several reasons, including personal choice, changed life situations resulting in lowered risk of HIV acquisition, intolerable toxicities, chronic nonadherence to the prescribed dosing regimen despite efforts to improve daily pill-taking, or acquisition of HIV infection. How to safely discontinue and restart PrEP use should be discussed with patients both when starting PrEP and when discontinuing PrEP. Protection from HIV infection will wane over 7-10 days after ceasing daily PrEP use[120-122]. Because some patients have acquired HIV infection soon after stopping PrEP use[29], alternative methods to reduce risk for HIV acquisition should be discussed, including indications for PEP and how to access it quickly if needed.

Upon discontinuation for any reason, the following should be documented in the health record:

- HIV status at the time of discontinuation
- Reason for PrEP discontinuation
- Recent medication adherence and reported sexual risk behavior

For persons with incident HIV infection, see Persons with Documented HIV Infection. See also Clinical Providers' Supplement Section 8 for a suggested management protocol.

For persons with active hepatitis B infection, see Special Clinical Considerations.

Any person who wishes to resume taking PrEP medications after having stopped should undergo all the same pre-prescription evaluation as a person being newly prescribed PrEP, including an HIV test to establish that they are still without HIV infection. In addition, a frank discussion should clarify the changed circumstances since discontinuing medication that indicate the need to resume medication, and the commitment to take it.

Special Clinical Considerations

The patient with certain clinical conditions requires special attention and follow-up by the clinician.

Women who become pregnant or breastfeed while taking PrEP medication

Women without HIV infection who have sex partners with documented HIV infection may be at risk of HIV acquisition during attempts to conceive (i.e., sex without a condom). Pregnancy is associated with an increased risk of HIV acquisition[123]. Risk is substantial for women whose partners are not taking antiretroviral treatment medication or women whose partners are treated but not virally suppressed. Women whose partners have documented sustained viral load suppression are at effectively no risk of sexual acquisition of HIV infection (see page 32 above). The extent to which PrEP use further decreases risk of HIV acquisition when the male partner has a documented recent undetectable viral load is unknown.

However, clinicians providing pre-conception and pregnancy care to women who report their partners have HIV infection, may not be providing care to the male partner and so may not have access to their medical records documenting the recent viral load status of the partner with HIV infection[65]. When the HIV status of the male partner is unknown, the clinician should offer HIV testing for the partner. When the male partner is reported to have HIV infection but his recent viral load status is not known, is reported detectable, or cannot be documented as undetectable, PrEP use during the preconception period and pregnancy by the uninfected woman offers an additional tool to reduce the risk of sexual HIV acquisition. Both the FDA labeling information[6] and the perinatal antiretroviral treatment guidelines[124] permit off-label use in pregnancy. However, data directly related to the safety of PrEP use for a developing fetus are limited. Providers should discuss available information about potential risks and benefits of beginning or continuing PrEP during pregnancy so that an informed decision can be made. (See Clinical Providers' Supplement, Section 5 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf

In the PrEP trials with heterosexual women, medication was promptly discontinued for those who became pregnant, so the safety for exposed fetuses could not be adequately assessed. A single small study of periconception use of TDF in 46 uninfected women in HIV-discordant couples found no ill effects on the pregnancy and no HIV infections[125]. Additionally, TDF and FTC are widely used for the treatment of HIV infection and continued during pregnancies that occur[126-128]. The data on pregnancy outcomes in the Antiretroviral Pregnancy Registry provide no evidence of adverse effects among fetuses exposed to these medications[129].

Providers should educate HIV-discordant couples who wish to become pregnant about the potential risks and benefits of all available alternatives for safer conception[130,131] and if indicated make referrals for assisted reproduction therapies. Whether or not PrEP is elected, the HIV-infected partner should be prescribed effective antiretroviral therapy before conception attempts[124,132]: if the infected partner is male, to reduce the risk of transmission-related viral load in semen; and in both sexes, for the benefit of their own health[133].

In addition, health care providers are strongly encouraged to prospectively and anonymously submit information about any pregnancies in which PrEP is used to the Antiretroviral Pregnancy Registry at http://www.apregistry.com/.

The safety of PrEP with TDF/FTC or TDF alone for infants exposed during lactation has not been adequately studied. However, data from studies of infants born to HIV-infected mothers and exposed to TDF or FTC through breast milk suggest limited drug exposure.[134,135] Additionally, the World Health Organization has recommended the use of TDF/FTC or 3TC/efavirenz for all pregnant and breastfeeding women for the prevention of perinatal and postpartum mother-to-child transmission of HIV[136]. Therefore, providers should discuss current evidence about the potential risks and benefits of beginning or continuing PrEP during breastfeeding so that an informed decision can be made[11]. (See Clinical Providers' Supplement, Section 5 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf

Patients with Chronic Active Hepatitis B Virus Infection

TDF and FTC are each active against both HIV infection and HBV infection and thus may prevent the development of significant liver disease by suppressing the replication of HBV. Only TDF, however, is currently FDA-approved for this use. Therefore, in persons with substantial risk of both HIV acquisition and active HBV infection, daily doses of TDF/FTC may be especially indicated.

All persons screened for PrEP who test positive for hepatitis B surface antigen (HBsAg) should be evaluated by a clinician experienced in the treatment of HBV infection. For clinicians without this experience, co-management with an infectious disease or a hepatic disease specialist should be considered. Patients should be tested for HBV DNA by the use of a quantitative assay to determine the level of HBV replication[137] before PrEP is prescribed and every 6-12 months while taking PrEP.

TDF presents a very high barrier to the development of HBV resistance. However, it is important to reinforce the need for consistent adherence to the daily doses of TDF/FTC to prevent reactivation of

[11]Although the DHHS Perinatal HIV Guidelines state that "pregnancy and breastfeeding are not contraindications for PrEP"[9], the FDA-approved package insert[6] says "If an uninfected individual becomes pregnant while taking TRUVADA for a PrEP indication, careful consideration should be given to whether use of TRUVADA should be continued, taking into account the potential increased risk of HIV-1 infection during pregnancy" and "mothers should be instructed not to breastfeed if they are receiving TRUVADA, whether they are taking TRUVADA for treatment or to reduce the risk of acquiring HIV-1.". Therefore both are currently off-label uses of Truvada.

HBV infection with the attendant risk of hepatic injury, and to minimize the possible risk of developing TDF-resistant HBV infection[138].

If PrEP is no longer needed to prevent HIV infection, a separate determination should be made to about whether to continue TDF/FTC as a means of providing TDF to treat HBV infection. Acute flares resulting from the reactivation of HBV infection have been seen in HIV-infected persons after the cessation of TDF and other medications used to treat HBV infection. Such flares have not yet been seen in HIV-uninfected persons with chronic active HBV infection who have stopped taking TDF-containing PrEP regimens. Nonetheless, when such patients discontinue PrEP, they should continue to receive care from a clinician experienced in the management of HBV infection so that if flares occur, they can be detected promptly and treated appropriately.

Patients with Chronic Renal Failure

HIV-uninfected patients with chronic renal failure, as evidenced by an eCrCl of <60 ml/min, should not take PrEP because the safety of TDF/FTC for such persons was not evaluated in the clinical trials. TDF is associated with modestly reduced renal function when used as part of an antiretroviral treatment regimen in persons with HIV infection (which itself can affect renal function). Because other HIV prevention options are available, the only PrEP regimen proven effective to date (TDF/FTC) and approved by FDA for PrEP is not indicated for persons with chronic renal failure.[6]

Adolescent Minors

As a part of primary health care, HIV screening should be discussed with all adolescents who are sexually active or have a history of injection drug use. Parental/guardian involvement in an adolescent's health care is often desirable but is sometimes contraindicated for the safety of the adolescent. However, laws and regulations that may be relevant for PrEP-related services (including HIV testing), such as those concerning consent, confidentiality, parental disclosure, and circumstances requiring reporting to local agencies, differ by jurisdiction. Clinicians considering providing PrEP to a person under the age of legal adulthood (a minor) should be aware of local laws, regulations, and policies that may apply[1139].

Although the FDA labeling information specifies PrEP indications for "adults," an age above which an adolescent is considered an adult is not provided.[6] None of the completed PrEP trials have included persons under the age of 18. Therefore, clinicians should consider carefully the lack of data on safety and effectiveness of PrEP taken by persons under 18 years of age, the possibility of bone or other toxicities among youth who are still growing, and the safety evidence available when TDF/FTC is used in treatment regimens for HIV-infected youth[140,141]. These factors should be weighed against the potential benefit of providing PrEP for an individual adolescent at substantial risk of HIV acquisition.

Nonoccupational Postexposure Prophylaxis

Persons not receiving PrEP who seek care within 72 hours after an isolated sexual or injection-related HIV exposure should be evaluated for the potential need for nPEP[119]. If the exposure is isolated (e.g., sexual assault, infrequent condom failure), nPEP should be prescribed, but PrEP or other continued antiretroviral medication is not indicated after completion of the 28-day PEP course.

Persons who repeatedly seek nPEP or who are at risk for ongoing HIV exposures should be evaluated for possible PrEP use after confirming they have not acquired HIV infection[142]. Because HIV infection has been reported in association with exposures soon after completing an nPEP course, daily PrEP may be more protective than repeated intermittent episodes of nPEP. Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of nPEP should be offered PrEP at the conclusion of their 28-day nPEP medication course. Because no definitive evidence exists that prophylactic antiretroviral use delays seroconversion, and nPEP is highly effective when taken as prescribed, a gap is unnecessary between ending nPEP and beginning PrEP. Upon documenting HIV-negative status, preferably by using a laboratory-based Ag/Ab test, daily use of the fixed dose combination of TDF (300mg) and FTC (200 mg) can begin immediately for patients for whom PrEP is indicated. See Clinical Providers' Supplement Section 9 for a recommended transition management strategy.

In contrast, patients fully adhering to a daily PrEP regimen do not need nPEP if they experience a potential HIV exposure while on PrEP. PrEP is highly effective when taken daily or near daily. For patients who report taking their PrEP medication sporadically, and those who did not take it within the week before the recent exposure, initiating a 28-day course of nPEP might be indicated. In that instance, all nPEP baseline and follow-up laboratory evaluations should be conducted. After the 28-day nPEP regimen is completed, if confirmed to be HIV uninfected, the previously experienced barriers to PrEP adherence should be evaluated and if addressed, daily PrEP regimen can be reinitiated.

Improving Medication Adherence

Data from the published studies of daily oral PrEP indicate that medication adherence is critical to achieving the maximum prevention benefit (see Table 4) and reducing the risk of selecting for a drug-resistant virus if non-adherence leads to HIV acquisition[143-145]. Three additional studies reinforce the need to prescribe, and support adherence to uninterrupted daily doses of TDF/FTC.

A study of the pharmacokinetics of directly observed TDF dosing in MSM in the STRAND trial found that the intracellular levels of the active form of TDF (tenofovir diphosphate), when applied to the drug detection-efficacy statistical model with iPrEx participants, corresponded to an HIV risk reduction efficacy of 99% for 7 doses per week, 96% for 4 doses per week, and 76% for 2 doses per week143. This finding adds to the evidence that despite some "forgiveness" for occasional missed doses for MSM, a high level of prevention efficacy requires a high level of adherence to daily medication. However, a laboratory study comparing vaginal and colorectal tissue levels of active metabolites of TDF and FTC found that drug levels associated with significant protection against HIV infection

required 6-7 doses per week (~85% adherence) for lower vaginal tract tissues but only 2 doses per week (28% adherence) for colorectal tissures146. This strongly suggests that there is less "forgiveness" for missed doses among women than among MSM.

A pilot study of daily TDF/FTC as PrEP with young MSM was stopped when the iPrEx trial results were reported.[147] Among the 68 men enrolled (mean age, 20 years; 53% African American; 40% Hispanic/Latino) plasma specimens were tested to objectively measure medication adherence. At week 4, 63% had detectable levels of tenofovir, but at week 24, only 20% had detectable levels of tenofovir. Two open-label safety studies with 243 young MSM (median age 19, 46% African American, 32% Latino/Hispanic) similarly found lower adherence in young adult men than has been reported in older adult men taking PrEP, and lower adherence with quarterly visits than with monthly visits[148].

In addition, a study with MSM and commercial sex workers in Kenya evaluated adherence to daily, fixed-interval (Mondays and Fridays), and coitally-timed (single post-coital) TDF/FTC dosing schedules by the use of pill bottles with caps monitored by an electronic medication event monitoring system (MEMS) and monthly interviews about sexual behavior[149]. Among the 67 men and 5 women in this study, 83% adhered to daily dosing, 55% to fixed-interval dosing, and 26% to post-coital dosing regimens. These findings suggest that adherence is better with daily dosing, as currently recommended, than with non-daily regimens (not yet proven effective as PrEP). These data confirm that medication education and adherence counseling (also called medication self-management) will need to be provided to support daily PrEP use.

A recent review of the antiretroviral treatment adherence studies over the past 15 years and adherence data from the completed PrEP trials suggests various approaches to effectively support medication adherence[150]. These approaches include educating patients about their medications; helping them anticipate and manage side effects; helping them establish dosing routines that mesh with their work and social schedules; providing reminder systems and tools; addressing financial, substance abuse, or mental health needs that may impede adherence; and facilitating social support.

Although many published articles address antiretroviral medication adherence among persons being treated for HIV infection, these findings may be only partially applicable to PrEP users. HIV treatment regimens include more than 2 drugs (commonly including more than 1 pill per day), resulting in an increased pill burden, and the possibility of side effects and toxicities with 3 or more drugs may occur that would not occur with TDF/FTC alone. The motivations of persons being treated for HIV infection and persons trying to prevent HIV infection may differ. Because PrEP will be used in otherwise healthy adults, studies of the use of medications in asymptomatic adults for the prevention of potential serious future health outcomes may also be informative for enhancing adherence to PrEP medications. The most cost-effective interventions for improving adherence to antihypertensive and lipid-lowering medications were initiated soon after the patients started taking medication and involved personalized, regularly scheduled education and symptom management (patients were aware that adherence was being monitored)[151]. Patients with chronic diseases reported that the most important factors in adherence to medications were incorporating medication into their daily routines, knowing that the

medications work, believing that the benefits outweigh the risks, knowing how to manage side effects, and low out-of pocket costs[152,153].

When initiating a PrEP regimen, clinicians must educate patients so that they understand clearly how to take their medications (i.e., when to take them, how many pills to take at each dose) and what to do if they experience problems (e.g., what constitutes a missed dose [number of hours after the failure to take a scheduled dose], what to do if they miss a dose). Patients should be told to take a single missed dose as soon as they remember it, unless it is almost time for the next dose. If it is almost time for the next dose, patients should skip the missed dose and continue with the regular dosing schedule.

Side effects can lead to non-adherence, so clinicians need a plan for addressing them. Clinicians should tell patients about the most common side effects and should work with patients to develop a specific plan for handling them, including the use of specific over-the-counter medications that can mitigate symptoms. The importance of using condoms during sex, especially for patients who decide to stop taking their medications, should be reinforced.

Box D: Key Components of Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them

Using a broad array of a health care professionals (e.g., physicians, nurses, case-managers, physician assistants, clinic-based and community pharmacists) that work together on a health care team to influence and reinforce adherence instructions[154] significantly improves medication adherence and may alleviate the time constraints of individual providers[155,156]. This broad-team approach may also provide a larger number of providers to counsel patients about self-management of behavioral risks.

For additional information on adherence counseling, see the Clinical Providers' Supplement, Section 10 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf.

Reducing HIV Risk Behaviors

The adoption and the maintenance of safer behaviors (sexual, injection, and other substance abuse) are critical for the lifelong prevention of HIV infection and are important for the clinical management of persons prescribed PrEP.

Video-based interventions such as Safe in the City, which make use of waiting-room time rather than clinician time[150,157], have reduced STI incidence in a general clinic population. However, they take a general approach, so they do not allow tailoring to the sexual risk-reduction needs of individual patients (e.g., as partners change, PrEP is initiated or discontinued).

Interactive, client-centered counseling (in which content is tailored to a patient's sexual risk behaviors and the situations in which risks occur), in conjunction with goal-setting strategies is effective in HIV prevention[142,158-160]. An example of this method is Project Respect: although this counseling protocol alone did not reduce HIV incidence significantly, 20-minute clinical counseling sessions to develop and review patient-specific, incremental risk-reduction plans led to reduced incidence of STIs in a heterosexual population,[161] . Project Aware included MSM and heterosexuals attending STD clinics and provided a single brief counseling session (using the Respect-2 protocol) while conducting rapid HIV testing. There was no reduction in the incidence of STIs attributed to counseling[162]. However, in the context of PrEP delivery, brief, repeated counseling sessions can take advantage of multiple visits for follow-up care[163] while addressing the limited time available for individual visits[157] and the multiple prevention[155,156] and treatment topics that busy practitioners need to address.

Reducing or eliminating injection risk practices can be achieved by providing access to drug treatment and relapse prevention services (e.g., methadone, buprenorphine for opiate users) for persons who are willing to participate[164]. For persons not able (e.g., on a waiting list or lacking insurance) or not motivated to engage in drug treatment, providing access to unused injection equipment through syringe service programs (where available), prescriptions for syringes or purchase from pharmacies without a prescription (where legal) can reduce HIV exposure. In addition, providing or referring for cognitive or behavioral counseling and any indicated mental health or social services may help reduce risky injection practices. See the Substance Abuse Treatment and Mental Health Treatment Locators at http://findtreatment.samhsa.gov/.

For additional information on risk reduction interventions, see Clinical Providers' Supplement, Section 11 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf.

Box E: Key Components of Behavioral Risk-Reduction Counseling

Establish trust and 2-way communication

Provide feedback on HIV risk factors identified during sexual and substance use history taking

- Elicit barriers to, and facilitators of, consistent condom use
- Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts

- Assist patient to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
- Identify and address anticipated barriers to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner

- Acknowledge the effort required for behavior change
- Reinforce success
- If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

Financial Case-Management Issues for PrEP

One critical component in providing PrEP medications and related clinical and counseling services is identifying insurance and other reimbursement sources. Although some commercial insurance and employee benefits programs have defined policies for the coverage of PrEP, others have not yet done so. Similarly, public insurance sources vary in their coverage policy. Most public and private insurers cover PrEP but co-pay, co-insurance, and prior authorization policies differ.

For patients who do not have health insurance, whose insurance does not cover PrEP medication, and whose personal resources are inadequate to pay out-of-pocket, Gilead Sciences has established a PrEP medication assistance program. In addition to providing Truvada to providers for eligible patients and access to free HIV testing, the program provides co-pay assistance for medication and free condoms to patients on request[165]. Providers may obtain applications for their patients at https://start.truvada.com/. In addition, a few states and cities have PrEP-specific financial assistance programs (check with your local health department).

Decision Support, Training and Technical Assistance

Decision support systems (electronic and paper), flow sheets, checklists (see Clinical Providers' Supplement, Section 1 for a PrEP provider/patient checklist at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf, feedback reminders, and involvement of nurse clinicians and pharmacists will be helpful in managing the many steps indicated for the safe use of PrEP and to increase the likelihood that patients will follow them. Often these systems are locally developed but may become available from various sources including training centers and Web sites funded by government agencies; professional associations, or interested private companies. Examples include downloadable applications (widgets) to support the delivery of nPEP or locate nearby sites for

confidential HIV tests (http://www.hivtest.org); and confidential commercial services to electronically monitor medication-taking, send text message reminders, or provide telephone assistance to help patients with problems concerning medication adherence.

Training and technical assistance in providing components of PrEP-related services, medications, and counseling are available at the following Web sites:

- PrEPline: National Clinician's Consultation Center (http://nccc.ucsf.edu/clinical-resources/prep-guidelines-and-resources/)
- National PrEP Clinician Locator (https://preplocator.org/)
- AIDS Info (http://www.aidsinfo.nih.gov, http://www.aids.gov)
- The National Network of STD/HIV Prevention Training Centers (http://nnptc.org/)
- The AIDS Education Training Centers National Resource Center (http://www.aids-ed.org)
- The Addiction Technology Transfer Center Network (http://www.attcnetwork.org)

Related Guidelines

This document is consistent with several other guidelines from several organizations related to sexual health, HIV prevention, and the use of antiretroviral medications. Clinicians should refer to these other documents for detailed guidance in their respective areas of care.

- Screening For HIV: Current Recommendations USPSTF, 2013[167]
- Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings[73]
- Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men — United States, 2017[169]
- Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents[80]
- Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States[74]
- Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Non-occupational Exposure to HIV -United States, 2017[119]
- Sexually Transmitted Diseases Treatment Guidelines, 2015[93]
- Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection[107]
- Expedited Partner Therapy in the Management of Sexually Transmitted Diseases, 2006[110]
- Guidance on the Use of Expedited Partner Therapy in the Treatment of Gonorrhea. 2016[109]
- Behavioral counseling to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement[159]
- Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection[168]
- Hepatitis C guidance: AASLD-I DSA recommendations for testing, managing, and treating adults infected with hepatitis C virus[92]

- Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: summary guidance from CDC and the U.S. Department of Health and Human Services[72]

Appendices

APPENDIX 1 GRADING OF STRENGTH OF RECOMMENDATIONS AND QUALITY OF EVIDENCE

Key recommendations in this guideline are based on the review of published scientific evidence and expert opinions. For details on the guidelines development process used, see the Clinical Providers' Supplement, Section 14 at https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep-provider-supplement-2017.pdf.

Using the same grading system as the DHHS antiretroviral treatment guidelines[80], these key recommendations are rated with a letter to indicate the strength of the recommendation and with a numeral to indicate the quality of the combined evidence supporting each recommendation.

Table 12: Rating Scheme for Recommendations

A. Strong recommendation for the statement	**I.** One or more well-executed randomized, controlled trials with clinical outcomes, validated laboratory endpoints, or both
B. Moderate recommendation for the statement	**II.** One or more well-executed, nonrandomized trials or observational cohort studies with clinical outcomes
C. Optional recommendation for the statement	**III.** Expert opinion

The quality of scientific evidence ratings in Table 2 are based on the GRADE rating system.[38]

Table 13: Criteria for rating quality of scientific evidence

Type of evidence	Randomized trial = high Observational study = low Any other evidence = very low
Decrease grade if[a]	▪ Serious or very serious limitation to study quality ▪ Important inconsistency ▪ Some or major uncertainty about directness ▪ Imprecise or sparse data ▪ High probability of reporting bias
Increase grade if[a]	▪ Strong evidence of association – significant relative risk >2 (<0.5) based on consistent evidence from 2 or more observational studies, with no plausible confounders (+1) ▪ Very strong evidence of association – significant relative risk of >5 (<0.2) based on direct evidence with no major threats to validity (+2) ▪ Evidence of a dose-response gradient (+1) ▪ All plausible confounders would have reduced the effect (+1)
Range	High-quality evidence Moderate-quality evidence Low-quality evidence Very-low quality evidence

[a] Each quality criterion can reduce or increase the quality by 1 or, if very significant, by 2 levels.
Source: http://www.gradeworkinggroup.org/FAQ/evidence_qual.htm

References

1. Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquir Immune Defic Syndr.* 2013;64(1):79-86.

2. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med.* 2010;363(27):2587-2599.

3. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med.* 2012;367(5):399-410.

4. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med.* 2012;367(5):423-434.

5. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet.* 2013;381(9883):2083-2090.

6. Gilead Sciences. Truvada Package Insert. 2017. http://gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf. Accessed July 26, 2017.

7. Food and Drug Administration. Truvada approved to reduce the risk of sexually transmitted HIV in people who are not infected with the virus. 2012; http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm312264.htm. Accessed 6 August 2012.

8. Food and Drug Administration. Background package for NDA 21-752/Supplement 30. 2012. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteeMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM303213.pdf. Accessed February 18, 2014.

9. Fonner VA, Dalglish SL, Kennedy CE, et al. Effectiveness and safety of oral HIV pre-exposure prophylaxis (PrEP) for all populations: A systematic review and meta-analysis. *AIDS.* 2016;30-(12):1973-1983.

10. Centers for Disease C, Prevention. Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men. *MMWR. Morbidity and mortality weekly report.* 2011;60(3):65-68.

11. Centers for Disease Control, Prevention. Interim guidance for clinicians considering the use of preexposure prophylaxis for the prevention of HIV infection in heterosexually active adults. *MMWR. Morbidity and mortality weekly report.* 2012;61(31):586-589.

12. Centers for Disease Control, Prevention. Update to interim guidance for preexposure prophylaxis (PrEP) for the prevention of HIV infection: PrEP for injecting drug users. *MMWR. Morbidity and mortality weekly report.* 2013;62(23):463-465.

13. Centers for Disease Control and Prevention. Fact sheet: HIV incidence: Estimated annual infections in the U.S., 2008-2014-Overall and by transmission route. https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-incidence-fact-sheet_508.pdf Accessed 27 Feb 2017.

14. Centers for Disease Control and Prevention. *HIV Surveillance Report,* 2015; vol 27. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2015-vol-27.pdf Accessed 27 Feb 2017.

15. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human-immunodeficiency-virus Type-1 with zidovudine treatment. *N Engl J Med.* 1994;331(18):1173-1180.

16. Centers for Disease Control and Prevention. Update: provisional Public Health Service recommendations for chemoprophylaxis after occupational exposure to HIV. *Morbidity and Mortality Weekly Reports.* 1996;45(22):468-472.

17. Centers for Disease Control and Prevention. Public Health Service guidelines for the management of health-care worker exposures to HIV and recommendations for postexposure prophylaxis. *Morbidity and Mortality Reports and Recommendations.* 1998;47(RR-7):1-34.

18. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med.* 1997;337(21):1485-1490.

19. Deutsch MB, Glidden DV, Sevelius J, et al. HIV pre-exposure prophylaxis in transgender women: A subgroup analysis of the iPrEx trial. *Lancet HIV.* 2015;2(12):e512-e519.

20. Liu AY, Vittinghoff E, Sellmeyer DE, et al. Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. *PloS One.* 2011;6(8):e23688.

21. Hosek SG, Siberry G, Bell M, et al. The acceptability and feasibility of an HIV preexposure prophylaxis (PrEP) trial with young men who have sex with men. *J Acquir Immune Defic Syndr.* 2013;62(4):447-456.

22. Molina JM, Capitant C, Spire B, et al. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med.* 2015;373(23):2237-2246.

23. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis.* 2014;14(9):820-829.

24. McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet.* 2016;387 North American Edition(10013):53-60.

25. Volk JE, Marcus JL, Phengrasamy T, et al. No new HIV infections with increasing use of HIV preexposure prophylaxis in a clinical practice setting. *Clin Infect Dis.* 2015;61(10):1601-1603.

26. Marcus JL, Hurley LB, Nguyen DP, Silverberg MJ, Volk JE. Redefining HIV Preexposure Prophylaxis Failures. *Clin Infect Dis.* 2017:cix593.

27. Liu AY, Cohen SE, Vittinghoff E, et al. Preexposure prophylaxis for HIV infection integrated with municipal-and community-based sexual health services. *JAMA Internal Medicine.* 2016;176(1):75-84.

28. Molina JM, Charreau I, Spire B, et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. *Lancet HIV.* 2017: online first: available at : http://dx.doi.org/10.1016/S2352-3018(17)30089-9

29. Murnane PM, Celum C, Mugo N, et al. Efficacy of preexposure prophylaxis for HIV-1 prevention among high-risk heterosexuals: subgroup analyses from a randomized trial. *AIDS.* 2013;27(13):2155-2160.

30. Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med.* 2012;367(5):411-422.

31. Peterson L, Taylor D, Roddy R, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: A phase 2, double-blind, randomized, placebo-controlled trial. *PLoS Clin Trial.* 2007;2(5):e27.

32. Marrazzo JM, Ramjee G, al . Tenofovir-based preexposure prophylaxis for HIV infection among African women. *N Engl J Med.* 2015; 372(6):509-18.

33. Baeten J. What Can the twisted tale of PrEP results teach us? *Conference on Retroviruses and Opportunistic Infections* 2012; http://www.retroconference.org/2012b/Abstracts/45269.htm. Accessed 21 April 2012.

34. Martin M, Vanichseni S, Suntharasamai P, et al. Factors associated with the uptake of and adherence to HIV pre-exposure prophylaxis in people who have injected drugs: an

observational, open-label extension of the Bangkok Tenofovir Study. *Lancet HIV.* 2017; 4(2): e59-e65.

35. Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction--GRADE evidence profiles and summary of findings tables. *J Clin Epidemiology.* 2011;64(4):383-394.

36. Wimberly YH, Hogben M, Moore-Ruffin J, Moore SE, Fry-Johnson Y. Sexual history-taking among primary care physicians. *J Natl Med Assoc.* 2006;98(12):1924-1929.

37. Kurth AE, Holmes KK, Hawkins R, Golden MR. A national survey of clinic sexual histories for sexually transmitted infection and HIV screening. *Sexually Transmitted Diseases* 2005;32(6):370-376.

38. Laws MB, Bradshaw YS, Safren SA, et al. Discussion of sexual risk behavior in HIV care is infrequent and appears ineffectual: A Mixed Methods Study. *AIDS Behav.* 2011;15(4):812-822.

39. Metsch LR, Pereyra M, del Rio C, et al. Delivery of HIV prevention counseling by physicians at HIV medical care settings in 4 US cities. *Am J Public Health.* 2004;94(7):1186-1192.

40. Duffus WA, Barragan M, Metsch L, et al. Effect of physician specialty on counseling practices and medical referral patterns among physicians caring for disadvantaged human immunodeficiency virus-infected populations. *Clin Infect Dis.* 2003;36(12):1577-1584.

41. Smith A, Le B, Finlayson T, Oster A, DiNenno E. Prevalence and awareness of HIV infection among men who have sex with men-21 cities, United States, 2008. *Morbidity and Mortality Weekly Report.* 2010;59(37):1201-1207.

42. Bernstein KT, Liu KL, Begier EM, Koblin B, Karpati A, Murrill C. Same-sex attraction disclosure to health care providers among New York City men who have sex with men: implications for HIV testing approaches. *Arch Intern Med.* 2008;168(13):1458-1464.

43. Menza TW, Hughes JP, Celum CL, Golden MR. Prediction of HIV acquisitiona men who have sex with men. *Sexually Transmitted Diseases.* 2009;36(9):547-555.

44. Smith DK, Pals SL, Herbst JH, Shinde S, Carey JW. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr.* 2012;60(4):421-427.

45. Pinkerton SD, Abramson PR. Effectiveness of condoms in preventing HIV transmission. *Soc Sci Med.* 1997;44(9):1303-1312.

46. Jenness SM, Neaigus Alan, Murrill CS, Wendel T, Forgione L, Hagan H. Estimated HIV incidence among high-risk in New York City, 2007. *J Acquir Immune Defic Syndr.* 2011;56(2):193-197.

47. LaLota M, Beck D, Metsch L, et al. HIV seropositivity and correlates of infection among heterosexually active adults in high-risk areas in South Florida. *AIDS Behav.* 2011;15(6):1259-1263.

48. Neaigus A, Miller M, Gyarmathy VA, Friedman SR. HIV heterosexual sexual risk from injecting drug users among HIV-seronegative noninjecting heroin users. *Substance Use & Misuse.* 2011;46(2-3):208-217.

49. Chan AW, Pristach EA, Welte JW. Detection by the CAGE of alcoholism or heavy drinking in primary care outpatients and the general population. *Journal of substance abuse.* 1994;6(2):123-135.

50. Bastiaens L, Riccardi K, Sakhrani D. The RAFFT as a screening tool for adult substance use disorders. *The American journal of drug and alcohol abuse.* 2002;28(4):681-691.

51. Knight JR, Sherritt L, Shrier LA, Harris SK, Chang G. Validity of the CRAFFT substance abuse screening test among adolescent clinic patients. *Archives of pediatrics & adolescent medicine.* 2002;156(6):607-614.

52. Halkitis PN, Pollock JA, Pappas MK, et al. Substance use in the MSM population of New York City during the era of HIV/AIDS. *Substance Use & Misuse.* 2011;46(2-3):264-273.

53. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev.* 2002(1):CD003255.

54. Smith DK, Herbst JH, Zhang X, Rose CE. Condom effectiveness for HIV prevention by consistency of use among men who have sex with men in the United States. *J Acquir Immune Defic Syndr.* 2015;68(3):337-344.

55. Ahmed S, Lutalo T, Wawer M, et al. HIV incidence and sexually transmitted disease prevalence associated with condom use: a population study in Rakai, Uganda. *AIDS.* 2001;15(16):2171-2179.

56. Koblin B, Chesney M, Coates T, Team ES. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. *Lancet.* 2004;364(9428):41-50.

57. Reece M, Herbenick D, Schick V, Sanders SA, Dodge B, Fortenberry JD. Condom use rates in a national probability sample of males and females ages 14 to 94 in the United States. *The Journal of Sexual Medicine.* 2010;7:266-276.

58. Peterman TA, Tian LH, Warner L, et al. Condom use in the year following a sexually transmitted disease clinic visit. *International journal of STD & AIDS.* 2009;20(1):9-13.

59. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, Hakim JG, Kumwenda J, Grinsztejn B, Pilotto JH, Godbole SV. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med.* 2016;;375(9):830-9.

60. Rodger AJ, Cambiano V, Bruun T, et al.; PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA.* 2016;316:171–81.

61. Centers for Disease Control and Prevention. Dear Colleague: National Gay Men's HIV/AIDS Awareness Day (NGMHAAD) -- September 27, 2017. 2017; https://www.cdc.gov/hiv/library/dcl/dcl/092717.html. Accessed October 3, 2017.

62. Crepaz N, Tang T, Marks G, Hall H. VIral suppression patterns among persons in the United States with diagnosed HIV infection in 2014. *Ann Intern Med.* 2017;167(6):446-447.

63. Gardner EM, McLees MP, Steiner JF, Del Rio C, Burman WJ. The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clin Infect Dis.* 2011;52(6):793-800.

64. Centers for Disease C, Prevention. HIV infection and HIV-associated behaviors among injecting drug users - 20 cities, United States, 2009. *MMWR. Morbidity and mortality weekly report.* 2012;61(8):133-138.

65. Strathdee SA, Stockman JK. Epidemiology of HIV among injecting and non-injecting drug users: current trends and implications for interventions. *Curr HIV/AIDS Rep.* 2010;7(2):99-106.

66. U.S. Preventive Services Task Force. Screening for Illicit Drug Use. 2012; http://www.uspreventiveservicestaskforce.org/uspstf08/druguse/drugrs.htm#summary. Accessed August 20, 2013.

67. Boileau C, Bruneau J, Al-Nachawati H, Lamothe F, Vincelette J. A prognostic model for HIV seroconversion among injection drug users as a tool for stratification in clinical trials. *J Acquir Immune Defic Syndr.* 2005;39(4):489-495.

68. Smith DK, Pan Y, Rose CE, et al. A brief screening tool to assess the risk of contracting HIV infection among active injection drug users. *Journal of addiction medicine.* 2014;9(3):226-232.

69. Centers for Disease C, Prevention. Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: summary guidance from CDC and the U.S. Department of Health and Human Services. *MMWR Recomm Rep.* 2012;61(RR-5):1-40.

70. Centers for Disease Control and Prevention, Branson BM, Handsfield HH, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *Morbidity and Mortality Reports and Recommendations.* 2006;September 22, 2006 / 55(RR14);1-17.

71. DiNenno EA. Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men—United States, 2017. *MMWR. Morbidity and mortality weekly report.* 2017;66.

72. Mimiaga MJ, Reisner SL, Bland S, et al. Health system and personal barriers resulting in decreased utilization of HIV and STD testing services among at-risk black men who have sex with men in Massachusetts. *AIDS patient care and STDs.* 2009;23(10):825-835.

73. Stekler JD, Ure G, O'Neal JD, et al. Performance of Determine Combo and other point-of-care HIV tests among Seattle MSM. *J Clin Virol.* 2016;76:8-13.

74. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: Updated recommendations. 2014; http://dx.doi.org/10.15620/cdc.23447. Accessed August 8, 2016.

75. Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. *Curr Opin HIV AIDS.* 2008;3(1):10-15.

76. Rich JD, Mylonakis E, Flanigan TP. Misdiagnosis of HIV infection - Response. *Ann Intern Med.* 1999;131(7):547-548.

77. Wu H, Cohen SE, Westheimer E, Gay CL, Hall L, Rose C, Hightow-Weidman LB, Gose S, Fu J, Peters PJ. Diagnosing acute HIV infection: The performance of quantitative HIV-1 RNA testing (viral load) in the 2014 laboratory testing algorithm. *J Clin Virol.* 2017;93:85-6.

78. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. 2017. http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf. Accessed July 26, 2017.

79. Cooper RD, Wiebe N, Smith N, Keiser P, Naicker S, Tonelli M. systematic review and meta-analysis: Renal safety of tenofovir disoproxil fumarate in HIV-infected patients. *Clin Infect Dis.* 2010;51(5):496-505.

80. Hall AM, Hendry BM, Nitsch D, Connolly JO. Tenofovir-associatedk toxicity in HIV-infected patients: A review of the evidence. *American Journal of Kidney Diseases.* 2011;57(5):773-780.

81. Phair J, Palella F. Renal disease in HIV-infected individuals. *Curr Opin HIV AIDS*. 2011;6(4):285-289.

82. Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. *Nephron*. 1976;16(1):31-41.

83. Wargo KA, Eiland EH, 3rd, Hamm W, English TM, Phillippe HM. Comparison of the modification of diet in renal disease and Cockcroft-Gault equations for antimicrobial dosage adjustments. *Ann Pharmacother*. 2006;40(7-8):1248-1253.

84. Rostoker G, Andrivet P, Pham I, Griuncelli M, Adnot S. Accuracy and limitations of equations for predicting the glomerular filtration rate during follow-up of patients with non-diabetic nephropathies. *BMC nephrology*. 2009;10:16.

85. Wolitski RJ, Fenton KA. Sexual health, HIV, and sexually transmitted infections among gay, bisexual, and other men who have sex with men in the United States. *AIDS Behav*. 2011;15 Suppl 1:S9-17.

86. van der Helm JJ, Prins M, del Amo J, et al. The hepatitis C epidemic among HIV-positive MSM: incidence estimates from 1990 to 2007. *AIDS*. 2011;25(8):1083-1091.

87. Gatanaga H, Hayashida T, Tanuma J, Oka S. Prophylactic effect of antiretroviral therapy on hepatitis B virus infection. *Clin Infect Dis*. 2013;56(12):1812-1819.

88. Moyer VA. Screening for hepatitis C virus infection in adults: US Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2013;159(5):349-357.

89. Hoornenborg E, Achterbergh RCA, Schim van der Loeff MF, et al. MSM starting preexposure prophylaxis are at risk of hepatitis C virus infection. *AIDS*. 2017;31(11):1603-1610.

90. Charre C, Cotte L, Kramer R, Miailhes P, Godinot M, Koffi J, Scholtès C, Ramière C. Hepatitis C virus spread from HIV-positive to HIV-negative men who have sex with men. *PloS One*. 2018;13(1):e0190340.

91. Volk JE, Marcus JL, Phengrasamy T, Hare CB. Incident hepatitis C virus infections among users of HIV preexposure prophylaxis in a clinical practice setting. *Clin Infect Dis*. 2015;60(11):1728-9.

92. AASLD-IDSA. HCV testing and linkage to care. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org/full-report/hcv-testing-and-linkage-care. Accessed February 20, 2018.

93. Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines (2015). *Morbidity and Mortality Recommendations and Reports*. 2015;64(RR3):1-137.

94. Centers for Disease Control and Prevention. 2016 Sexually Transmitted Disease Surveillance; National Profile-Overview: Chlamydia. 2017; https://www.cdc.gov/std/stats16/chlamydia.htm. Accessed October 13, 2017.

95. Barbee LA, Tat S, Dhanireddy S, Marrazzo JM. Implementation and operational research: effectiveness and patient acceptability of a sexually transmitted infection self-testing program in an HIV care setting. *J Acquir Immune Defic Syndr*. 2016;72(2):e26-e31.

96. Freeman AH, Bernstein KT, Kohn RP, Philip S, Rauch LM, Klausner JD. Evaluation of self-collected versus clinician-collected swabs for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae pharyngeal infection among men who have sex with men. *Sexually transmitted diseases*. 2011;38(11):1036-1039.

97. Lunny C, Taylor D, Hoang L, et al. Self-collected versus clinician-collected sampling for Chlamydia and Gonorrhea screening: a systemic review and meta-analysis. *PloS One*. 2015;10(7):e0132776.

98. Hunte T, Alcaide M, Castro J. Rectal infections with chlamydia and gonorrhoea in women attending a multiethnic sexually transmitted diseases urban clinic. *International journal of STD & AIDS*. 2010;21(12):819-822.

99. Trebach JD, Chaulk CP, Page KR, Tuddenham S, Ghanem KG. Neisseria gonorrhoeae and Chlamydia trachomatis among women reporting extragenital exposures. *Sexually transmitted diseases*. 2015;42(5):233.

100. Danby CS, Cosentino LA, Rabe LK, et al. Patterns of extragenital chlamydia and gonorrhea in women and men who have sex with men reporting a history of receptive anal intercourse. *Sexually transmitted diseases*. 2016;43(2):105-109.

101. Oster AM, Wertheim JO, Hernandez AL, Ocfemia MC, Saduvala N, Hall HI. Using Molecular HIV Surveillance Data to Understand Transmission Between Subpopulations in the United States. *J Acquir Immune Defic Syndr*. 2015;70(4):444-451.

102. Hurt CB, Beagle S, Leone PA, et al. Investigating a sexual network of black men who have sex with men: implications for transmission and prevention of HIV infection in the United States. *J Acquir Immune Defic Syndr*. 2012;61(4):515.

103. Copen CE, Chandra A, Febo-Vazquez I. Sexual behavior, sexual attraction, and sexual orientation among adults Aged 18-44 in the United States: Data From the 20113 National Survey of Family Growth. *National Health Statistics Reports*. 2016(88):1-14.

104. Justman J, Befus M, Hughes J, et al. Sexual behaviors of US women at risk of HIV acquisition: a longitudinal analysis of findings from HPTN 064. *AIDS Behav*. 2015;19(7):1327-1337.

105. Dombrowski JC. Do women need screening for extragenital gonococcal and chlamydial infections? *Sexually Transmitted Diseases.* 2015;42(5):240-241.

106. Tao G, Hoover KW, Nye MB, Peters PJ, Gift TL, Body BA. Infrequent testing of women for rectal chlamydia and gonorrhea in the United States. *Clin Infect Dis.* 2017.

107. Centers for Disease Control and Prevention. Recommendations for partner services programs for HIV infection, syphilis, gonorrhea, and chlamydial infection. *Morbidity and Mortality Reports and Recommendations.* 2008;57(RR09):1-63.

108. American College of Obstetrics and Gynecology. Committee Opinion: Expedited Partner Therapy in the Management of Gonorrhea and Chlamydial Infection. 2015; https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Expedited-Partner-Therapy-in-the-Management-of-Gonorrhea-and-Chlamydial-Infection. Accessed 12 October 2017.

109. Centers for Disease Control and Prevention. Guidance on the Use of Expedited Partner Therapy in the Treatment of Gonorrhea. 2016; https://www.cdc.gov/std/ept/gc-guidance.htm. Accessed 12 October 2017.

110. Centers for Disease Control and Prevention. Expedited partner therapy in the management of sexually transmitted diseases. 2006; https://www.cdc.gov/std/treatment/eptfinalreport2006.pdf. Accessed October 12, 2017

111 Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: implications for prevention of HIV-1 transmission. *Science Transl Med.* 2011;3(112):112-114.

112. Anderson PL, Kiser JJ, Gardner EM, Rower JE, Meditz A, Grant RM. Pharmacological considerations for tenofovir and emtricitabine to prevent HIV infection. *Journal of Antimicrobial Chemotherapy.* 2011;66(2):240-250.

113. Anderson PL. Pharmacology Considerations for HIV Prevention. 13th International Workshop on Clinical Pharmacology of HIV 2012; Barcelona, Spain.

114. McComsey GA, Tebas P, Shane E, et al. Bone disease in HIV infection: A practical review and recommendations for HIV care providers. *Clin Infect Dis.* 2010;51(8):937-946.

115. Yin MT, Overton ET. Increasing clarity on bone loss associated with antiretroviral initiation. *J Infect Dis.* 2011;203(12):1705-1707.

116. Mulligan K, Glidden D, Gonzales P, et al. Effects of emtricitabine/tenofovir on bone mineral density in seronegative men from 4 continents: DEXA results of the global iPrEx study. Paper presented at: Boston: 18th Conference on Retroviruses and Opportunistic Infections. 2011.

117. Kasonde M, Niska RW, Rose C, et al. Bone Mineral Density Changes among HIV-Uninfected Young Adults in a Randomised Trial of Pre-Exposure Prophylaxis with Tenofovir-Emtricitabine or Placebo in Botswana. *PloS One*. 2014;9(3):e90111.

118. Anderson P LJ, Buchbinder S, Guanira J, Montoya O, Casapia M, Bargg L, Bushman L, Glidden D, Grant R, and the iPrEx study team. Interpreting detection rates of intracellular FTC-TP and TFV-DP: The iPrEx trial. 18th Conference on Retroviruses and Opportunistic Infections; 2011; Boston, Massachusetts.

119. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral postexposure pophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. 2016. http://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf. Accessed November 1, 2017.

120. Seifert SM, Glidden DV, Meditz AL, et al. Dose response for starting and stopping HIV preexposure prophylaxis for men who have sex with men. *Clin Infect Dis*. 2015;60(5):804-810.

121. Seifert SM, Chen X, Meditz AL, et al. Intracellular tenofovir and emtricitabine anabolites in genital, rectal, and blood compartments from first dose to steady state. *AIDS Res Hum Retroviruses*. 2016;32(10-11):981-991.

122. Hendrix CW, Andrade A, Bumpus NN, et al. Dose frequency ranging pharmacokinetic study of tenofovir-emtricitabine after directly observed dosing in healthy volunteers to establish adherence benchmarks (HPTN 066). *AIDS Res Hum Retroviruses*. 2016;32(1):32-43.

123. Mugo NR, Heffron R, Donnell D, et al. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS*. 2011;25(15):1887-1895.

124. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. 2016. http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf. Accessed July 26, 2017.

125. Vernazza PL, Graf I, Sonnenberg-Schwan U, Geit M, Meurer A. Preexposure prophylaxis and timed intercourse for HIV-discordant couples willing to conceive a child. *AIDS*. 2011;25(16):2005-2008.

126. Siberry GK, Williams PL, Mendez H, et al. Safety of tenofovir use during pregnancy: early growth outcomes in HIV-exposed uninfected infants. *AIDS*. 2012;26(9):1151-1159.

127. Gibb DM, Kizito H, Russell EC, et al. Pregnancy and infant outcomes among HIV-infected women taking long-term ART with and without tenofovir in the DART trial. *PloS Med.* 2012;9(5):e1001217.

128. Mirochnick M, Best BM, Clarke DF. Antiretroviral pharmacology: special issues regarding pregnant women and neonates. *Clinics in perinatology.* 2010;37(4):907-927.

129. The Antiretroviral Pregnancy Registry. Interim Report: 1 January 1989 through 31 January 2017. 2017; http://www.apregistry.com/forms/interim_report.pdf. Accessed July 26, 2017.

130. Lampe MA, Smith DK, Anderson GJE, Edwards AE, Nesheim SR. Achieving safe conception in HIV-discordant couples: the potential role of oral preexposure prophylaxis (PrEP) in the United States. *Am J Obstet Gynecol.* 2011;204(6).

131. Brooks JT, Kawwass JF, Smith DK, et al. Effects of antiretroviral therapy to prevent HIV transmission to women in couples attempting conception when the man has HIV infection — United States, 2017. *MMWR Morb Mort Wkly Rep.* 2017;66:859-860.

132. Attia S, Egger M, Muller M, Zwahlen M, Low N. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. *AIDS.* 2009;23(11):1397-1404.

133. Cohen MS, McCauley M, Gamble TR. HIV treatment as prevention and HPTN 052. *Curr Opin HIV AIDS.* 2012;7(2):99-105.

134. Mugwanya KK, Hendrix CW, Mugo NR, et al. Pre-exposure Prophylaxis Use by Breastfeeding HIV-Uninfected Women: A Prospective Short-Term Study of Antiretroviral Excretion in Breast Milk and Infant Absorption. *PloS Med.* 2016;13(9):e1002132.

135. Benaboud S, Pruvost A, Coffie PA, et al. Concentrations of tenofovir and emtricitabine in breast milk of HIV-1-infected women in Abidjan, Cote d'Ivoire, in the ANRS 12109 TEmAA Study, Step 2. *Antimicrobial agents and chemotherapy.* 2011;55(3):1315-1317.

136. World Health Organization. Programmatic Update: Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. 2012. http://aidsdatahub.org/dmdocuments/Use_of_Antiretroviral_Drugs__for_Treating_Pregnant_Women.pdf . Accessed 16 August 2013.

137. Liaw Y-F, Chu C-M. Hepatitis B virus infection. *Lancet.* 2009;373(9663):582-592.

137. Hongthanakorn C, Chotiyaputta W, Oberhelman K, et al. Virological breakthrough and resistance in patients with chronic hepatitis B receiving nucleos(t)ide analogues in clinical practice. *Hepatology.* 2011;53(6):1854-1863.

139. Culp L, Caucci L. State adolescent consent laws and implications for HIV pre-exposure prophylaxis. *Am J Prev Med.* 2013;44(1 Suppl 2):S119-124.

140. Della Negra M, de Carvalho AP, de Aquino MZ, et al. A randomized study of tenofovir disoproxil fumarate in treatment-experienced HIV-1 infected adolescents. *Ped Infect Dis J.* 2012;31(5):469-473.

141. Purswani M, Patel K, Kopp JB, et al. Tenofovir Treatment Duration Predicts Proteinuria in a Multiethnic United States Cohort of Children and Adolescents With Perinatal HIV-1 Infection. *Ped Infect Dis J.* 2013;32(5):495-500.

142. Roland ME, Neilands TB, Krone MR, et al. A Randomized Noninferiority Trial of Standard Versus Enhanced Risk Reduction and Adherence Counseling for Individuals Receiving Post-Exposure Prophylaxis Following Sexual Exposures to HIV. *Clin Infect Dis.* 2011;53(1):76-83.

143. Abbas UL, Glaubius R, Mubayi A, Hood G, Mellors JW. Antiretroviral therapy and pre-exposure prophylaxis: Combined impact on HIV transmission and drug resistance in South Africa. *J Infect Dis.* 2013;208(2):224-234.

144. Celum C, Hallett TB, Baeten JM. HIV-1 prevention With ART and PrEP: Mathematical modeling insights into resistance, effectiveness, and public health impact. *J Infect Dis.* 2013;208(2):189-191.

145. Anderson PL, Glidden DV, Liu A, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. *Sci Transl Med.* 2012;4(151):151ra125.

146. Cottrell ML, Yang KH, Prince HMA, et al. A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. *J Infect Dis.* 2016;214(1):55-64.

147. Hosek S, Siberry G, Bell M, et al. The acceptability and feasibility of an HIV pre-exposure prophylaxis (PrEP) trial with young men who have sex with men (YMSM). *J Acquir Immune Defic Syndr.* 2012;62(4):447-456.

148. Koss CA, Hosek SG, Bacchetti P, et al. Comparison of Measures of Adherence to Human Immunodeficiency Virus Preexposure Prophylaxis Among Adolescent and Young Men Who Have Sex With Men in the United States. *Clin Infect Dis.* 2017:cix755-cix755.

149. Mutua G, Sanders E, Mugo P, et al. Safety and adherence to intermittent pre-exposure prophylaxis (PrEP) for HIV-1 in African men who have sex with men and female sex workers. *PloS One.* 2012;7(4):e33103..

150. Koenig LJ, Lyles C, Smith DK. Adherence to antiretroviral medications for HIV pre-exposure prophylaxis: lessons learned from trials and treatment studies. *Am J Prev Med.* 2013;44(1 Suppl 2):S91-98.

151. Chapman RH, Ferrufino CP, Kowal SL, Classi P, Roberts CS. The cost and effectiveness of adherence-improving interventions for antihypertensive and lipid-lowering drugs*. *Int J Clin Pract.* 2010;64(2):169-181.

152. Morello CM, Chynoweth M, Kim H, Singh RF, Hirsch JD. Strategies to improve medication adherence reported by diabetes patients and caregivers: Results of a taking control of your diabetes survey. *Ann Pharmacother.* 2011;45(2):145-153.

153. McHorney CA. The Adherence Estimator: a brief, proximal screener for patient propensity to adhere to prescription medications for chronic disease. *Curr Med Res Opin.* 2009;25(1):215-238.

154. Golub SA, Operario D, Gorbach PM. Pre-exposure prophylaxis state of the science: empirical analogies for research and implementation. *Curr HIV/AIDS Rep.* 2010;7(4):201-209.

155. Fiscella K, Epstein RM. So much to do, so little time: Care for the socially disadvantaged and the 15-minute visit. *Arch Intern Med.* 2008;168(17):1843-1852.

156. Yarnall KSH, Pollak KI, Ostbye T, Krause KM, Michener JL. Primary care: Is there enough time for prevention? *Am J Public Health.* 2003;93(4):635-641.

157. Warner L, Klausner JD, Rietmeijer CA, et al. Effect of a brief video intervention on incident infection among patients attending sexually transmitted disease clinics. *PloS Med.* 2008;5(6):919-927.

158. Lin JS, Whitlock E, O'Connor E, Bauer V. Behavioral counseling to prevent sexually transmitted infections: A systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2008;149(7):497-499.

159. U.S. Preventive Services Task Force. Behavioral counseling to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2008;149(7):491-496, W495.

160. Malotte CK. Brief risk-reduction counseling in clinical settings for HIV pre-exposure prophylaxis. *Am J Preventive Med.* 2013;44(1):S112-S118.

161. Kamb ML, Fishbein M, Douglas JM, Jr., et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. *JAMA.* 1998;280(13):1161-1167.

162. Metsch LR, Feaster DJ, Gooden L, et al. Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. *JAMA*. 2013;310(16):1701-1710.

163. Thrun MW. Provider-initiated HIV-risk behavior counseling in the context of HIV pre-exposure prophylaxis. *Am J Preventive Med.* 2013;44(1 Suppl 2):S108-111.

164. National Institute on Drug Abuse. Principles of drug addiction treatment: a Research-based guide. Third ed 2012: http://www.drugabuse.gov/publications/principles-drug-addiction-treatment. Accessed 20 August 2013.

165. National Alliance of State and Territorial AIDS Directors. Fact Sheet: Pharmaceutical company patient assistance programs and co-payment assistance programs for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). 2013; https://www.nastad.org/sites/default/files/PrEP-and-PEP-PAP-fact-sheet.pdf. Accessed 28 September 2013.

166. Centers for Disease Control and Prevention. Expedited partner therapy in the management of sexually transmitted diseases. 2006:1-52. http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf. Accessed 5 July 2011.

167. US Preventive Services Task Force. Screening For HIV: Current recommendations, U.S. Preventive Services Task Force. 2013. http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm. Accessed July 26, 2017.

168. Weinbaum CM, Williams I, Mast EE, et al. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. *MMWR Recomm Rep.* 2008;57(RR-8):1-20.

169. DiNenno EA, Prejean J, Irwin K, et al. Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men — United States, 2017. *MMWR Morb Mortal Wkly Rep.* 2017;66:830–832.

Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016

from the
Centers for Disease Control and Prevention,
U.S. Department of Health and Human Services

Update: Interim Statement Regarding Potential Fetal Harm from Exposure to Dolutegravir – Implications for HIV Post-exposure Prophylaxis (PEP). Please see attached file.

Disclaimers:

All material in this publication is in the public domain and may be used and reprinted without permission; citation as to source, however, is appreciated.

References to non-CDC sites on the Internet are provided as a service to readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed were current as of the date of publication.

This report describes use of certain drugs and tests for some indications that do not reflect labeling approved by the Food and Drug Administration at the time of publication. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

CONTENTS

I. List of Tables and Figures 5
II. Abbreviations and Acronyms 6
III. Disclosure of Potential Competing Interest 8
IV. Summary 8
IV-A. What Is New in This Update 8
IV-B. Summary of Guidelines 8
V. Introduction 10
VI. Evidence Review 11
VI-A. Possible Effectiveness of nPEP 11
V1-A1. oPEP Studies 11
V1-A2. Observational and Case Studies of nPEP 11
VI-A3. Postnatal Prophylaxis of Infants Born to HIV-infected Mothers 14
VI-A4. Animal Studies 14
VI-B. Possible Risks Associated with nPEP 15
VI-B1. Antiretroviral Side Effects and Toxicity 15
V1-B2. Selection of Resistant Virus 17
VI-B3. Effects of nPEP on Risk Behaviors 17
VI-C. Antiretroviral Use During Pregnancy 18
VI-D. Behavioral Intervention to Support Risk Reduction During nPEP Use 19
VI-E. Adherence to nPEP Regimens and Follow-up Visits 19
VI-F. nPEP Cost-effectiveness 21
VI-G. Attitudes, Policies, and Knowledge About nPEP Use Among Health Care Providers and Candidates for nPEP 21
VII. Patient Management Guidelines 23
VII-A. Initial Evaluation of Persons Seeking Care After Potential Nonoccupational Exposure to HIV 23
VII-A1. HIV Status of the Potentially Exposed Person 23
VII-A2. Timing and Frequency of Exposure 24
VII-A3. HIV Acquisition Risk from the Exposure 24
VII-A4. HIV Status of the Exposure Source 26
VII-B. Laboratory Testing 26
VII-B1. HIV Testing 28
VII-B2. Recognizing Acute HIV Infection at Time of HIV Seroconversion 28
VII-B3. STI Testing 29
VII-B4. HBV Testing 29

VII-B5. Pregnancy Testing 30
VII-B6. Baseline and Follow-up Testing to Assess Safety of Antiretroviral Use for nPEP 30
VII-C. Recommended Antiretroviral nPEP Regimens 30
VII-D. Prophylaxis for STIs and Hepatitis 38
VII-E. Considerations for All Patients Treated with Antiretroviral nPEP 39
VII-E1. Provision of nPEP Starter Packs or a 28-day Supply at Initiation 39
VII-E2. Expert Consultation 39
VII-E3. Facilitating Adherence 39
VII-E4. HIV Prevention Counseling 40
VII-E5. Providing PrEP After nPEP Course Completion 40
VII.E6. Providing nPEP in the Context of PrEP 40
VII-E7. Management of Source Persons with HIV Infection 41
VII-F. Additional Considerations 41
VII-F1. Reporting and Confidentiality 41
VII-F2. Special Populations 41
VII-F3. Special Legal and Regulatory Concerns 44
VII-F4. Potential Sources of Financial Assistance for nPEP Medication 44
VIII. Conclusion 45
VIII-A. Plans for Updating These Guidelines 46
IX. References 47
X. Appendices 59
Appendix 1A. Summary of Methods for nPEP Guidelines Development and Roles of Teams and Consultants 60
Appendix 1B. nPEP Guidelines Development Teams and Consultants 62
Appendix 1C. Financial Disclosures of Potential Competing Interest nPEP Guidelines Consultants and Working Group 64
Appendix 2. Literature Search Methods for the nPEP Guidelines 67
Appendix 3. Studies Reviewed for the nPEP Guidelines 68
Appendix 4. Consideration of Other Alternative HIV nPEP Antiretroviral Regimens 91

I. List of Tables and Figures

Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures 23

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act 25

Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens 27

Table 3. Clinical signs and symptoms of acute (primary) human immunodeficiency virus infection 28

Table 4. Hepatitis B virus screening serology 29

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP 31

Table 6. Formulations, cautions, and dose adjustments for antiretroviral medications in preferred and alternative nPEP regimens 33

Table 7. Antiretroviral medications that should not be used for nPEP among pregnant women 42

Figure 2. nPEP considerations summary 45

II. Abbreviations and Acronyms

3TC	lamivudine
Ab	antibody
Ag	antigen
Ag/Ab	antigen/antibody combination test
AIDS	acquired immunodeficiency syndrome
Anti-HBc	hepatitis B core antibody
Anti-HBs	hepatitis B surface antibody
aOR	adjusted odds ratio
ATV	atazanavir
ATV/r	ritonavir-boosted atazanavir
CAI	condomless anal intercourse
CA-NSI	community-acquired needlestick injury
CD4	CD4 T lymphocyte
CDC	Centers for Disease Control and Prevention
CI	confidence interval
d4T	stavudine
DDI	didanosine
DNA	deoxyribonucleic acid
DRV	darunavir
DRV/r	ritonavir-boosted darunavir
DTG	dolutegravir
DHHS	U.S. Department of Health and Human Services
ED	emergency department
EFV	efavirenz
ELISA	enzyme-linked immunosorbent assay
FDA	Food and Drug Administration
FTC	emtricitabine
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HIV	human immunodeficiency virus
IDV	indinavir
IDV/r	ritonavir-boosted indinavir
IFA	indirect fluorescent antibody
LPV	lopinavir

LPV/r	ritonavir-boosted lopinavir
MSM	gay, bisexual, and other men who have sex with men
NAAT	nucleic acid amplification test
NFV	nelfinavir
NIH	National Institutes of Health
NNRTI	non-nucleoside reverse transcriptase inhibitors
NRTI	nucleoside reverse transcriptase inhibitors
NVP	nevirapine
nPEP	nonoccupational postexposure prophylaxis
oPEP	occupational postexposure prophylaxis
PCR	polymerase chain reaction
PI	protease inhibitor
PrEP	preexposure prophylaxis
PWID	persons who inject drugs
OR	odds ratio
PCR	polymerase chain reaction
PEP	postexposure prophylaxis
PrEP	preexposure prophylaxis
QALY	quality-adjusted life year
RAL	raltegravir
RNA	ribonucleic acid
RPV	rilpivirine
RTV	ritonavir
SANE	Sexual Assault Nurse Examiner
SD	standard deviation
SIV	simian immunodeficiency virus
SHIV	simian human immunodeficiency virus
STI	sexually transmitted infection
TDF	tenofovir disoproxil fumarate
ZDV	zidovudine

III. Disclosure of Potential Competing Interest

nPEP Guidelines Consultants and Working Group Potential Competing Interest. The federal government employees who prepared this report have no competing interests with the manufacturers of the products discussed herein. See Appendixes 1A, 1B, and 1C for the definition of competing interests for persons involved in guidelines development and procedures for managing conflicts of interest, lists of names and affiliations of the nPEP guidelines development teams and consultants, and financial disclosures of potential competing interests.

IV. Summary

The purpose of these guidelines is to provide health care providers in the United States with updated guidelines to the 2005 U.S. Department of Health and Human Services nonoccupational postexposure prophylaxis (nPEP) recommendations[1] on the use of antiretroviral nPEP and other aspects of case management for persons with isolated exposure outside health care settings to blood, genital secretions, or other potentially infectious body fluids that might contain human immunodeficiency virus (HIV). The use of occupational PEP (oPEP) for case management for persons with possible HIV exposures occurring in health care settings are not addressed in this guideline; updated oPEP guidelines have been published separately.[2]

IV-A. What Is New in This Update

This update incorporates additional evidence regarding use of nonoccupational postexposure prophylaxis (nPEP) from animal studies, human observational studies, and consideration of new antiretroviral medications that were approved since the 2005 guidelines, some of which have improved tolerability. New features are inclusion of guidelines for the use of rapid antigen/antibody (Ag/Ab) combination HIV tests, for revised preferred and alternative 3-drug antiretroviral nPEP regimens, an updated schedule of laboratory evaluations of source and exposed persons, updated antimicrobial regimens for prophylaxis of sexually transmitted infections and hepatitis, and a suggested procedure for transitioning patients between nPEP and HIV preexposure prophylaxis (PrEP), as appropriate.

IV-B. Summary of Guidelines

- Health care providers should evaluate persons rapidly for nPEP when care is sought ≤72 hours after a potential nonoccupational exposure that presents a substantial risk for HIV acquisition.[a] [VI-A4] [VII-A2][b]
    - All persons considered for nPEP should have determination of their HIV infection status by HIV testing, preferably by using rapid combined Ag/Ab, or antibody blood tests. [VII-A1] [VII-B1]
    - If rapid HIV blood test results are unavailable, and nPEP is otherwise indicated, it should be initiated without delay and can be discontinued if the patient is later determined to have HIV infection already or the source is determined not to have HIV infection. [VII-A1]

---

[a] See Figure 1.

[b] Numbers in brackets refers readers to the section in these guidelines that provides the basis for the recommendation.

- nPEP is recommended when the source of the body fluids is known to be HIV-positive and the reported exposure presents a substantial risk for transmission. [VII-A]
- nPEP is not recommended when the reported exposure presents no substantial risk of HIV transmission. [VII-A]
- nPEP is not recommended when care is sought > 72 hours after potential exposure. [VI-A4] [VII-A] [VII-A2]
- A case-by-case determination about the nPEP is recommended when the HIV infection status of the source of the body fluids is unknown and the reported exposure presents a substantial risk for transmission if the source did have HIV infection. [VII-A]
- All persons offered nPEP should be prescribed a 28-day course of a 3-drug antiretroviral regimen.[a] [VII-B1] [VII-C]
    - The preferred regimen for otherwise healthy adults and adolescents
        - tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) with emtricitabine (200 mg) once daily ***plus***

          raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily. [VI-A2ci] [VII-C]
    - Alternative regimen for otherwise healthy adults and adolescents is
        - tenofovir DF (300 mg) with emtricitabine (FTC) (200 mg) once daily ***plus***

          darunavir (DRV) (800 mg) and ritonavir[a] (RTV) (100 mg) once daily. [VII-C]
    - Regimens are also provided for children, persons with decreased renal function, and pregnant women (see Table 6). [VII-C]
    - Health care providers considering using antiretroviral regimens for nPEP other than those listed in these guidelines as preferred or alternative are encouraged to consult with other health care providers who have expertise in antiretroviral medication use for similar patients (e.g., children, pregnant women, or those with such comorbid conditions as impaired renal function). [VII-C] [VII-E2]
- All persons evaluated for possible nPEP should be provided any indicated prevention, treatment, or supportive care for other exposure-associated health risks and conditions (e.g., bacterial sexually transmitted infections, traumatic injuries, hepatitis B virus and hepatitis C virus infection, or pregnancy). [VII] [VII-B3] [VII-B4] [VII-B5] [VII-D]
- All persons who report behaviors or situations that place them at risk for frequently recurring HIV exposures (e.g., injection drug use, or sex without condoms) or who report receipt of ≥ 1 course of nPEP in the past year should be provided risk-reduction counseling and intervention services, including consideration of preexposure prophylaxis. [VII-E4] [VII-E5]

---

[a] Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir and other protease inhibitors; it was not considered an additional drug when enumerating drugs in a regimen.

V. INTRODUCTION

The most effective methods for preventing human immunodeficiency virus (HIV) infection are those that protect against exposure. Antiretroviral therapy cannot replace behaviors that help avoid HIV exposure (e.g., sexual abstinence, sex only in a mutually monogamous relationship with an HIV-uninfected partner, consistent and correct condom use, abstinence from injection drug use, and consistent use of sterile equipment by those unable to cease injection drug use). Provision of antiretroviral medication after isolated sexual, injection drug use, or other nonoccupational HIV exposure, known as nonoccupational postexposure prophylaxis (nPEP), is less effective at preventing HIV infection than avoiding exposure.

In 2005, the U.S. Department of Health and Human Services (DHHS) released its first recommendations for nPEP use to reduce the risk for HIV infection after nonoccupational exposures to blood, genital secretions, and other body fluids that might contain HIV.[1] In 2012, updated guidelines on the use of occupational PEP (oPEP) for case management for persons with possible HIV exposures occurring in health care settings were published and are not addressed in this guideline.[2] Other organizations, including health departments, professional medical societies, and medical institutions, have developed guidelines, recommendations, and protocols for nPEP delivered to adults and children.[3-10]

This document updates the 2005 DHHS nPEP recommendations in response to new information regarding clinical experience for delivering nPEP, including using newer antiretroviral regimens and their side-effect profiles and cost-effectiveness of nPEP to prevent HIV infection for different exposure types. We describe in more detail the goals for the new guidelines, funding source of the guidelines, persons involved in guidelines development, definition of competing interest for persons involved in guidelines development and procedures for managing competing interest (Appendix 1A).

CDC scientists selected nPEP subject matter experts from the Food and Drug Administration (FDA), the National Institutes of Health (NIH), hospitals, clinics, health departments, and professional medical societies to participate as panelists to discuss recent developments in nPEP practice by CDC teleconferences in December 2011, and April 2012 (Appendix 1B). Any potential conflicts of interests reported by persons involved in developing the guidelines and the determination made for each of those potential conflicts are listed in Appendix 1C.

A working group of CDC HIV prevention scientists and other CDC scientists with expertise pertinent to the nPEP guidelines conducted nPEP-related systematic literature reviews. Appendix 2 summarizes the methods used to conduct that review, including databases queried, topics addressed, search terms, search dates, and any limitations placed on the searches (i.e., language, country, population, and study type). All studies identified through the literature search were reviewed and included in the body of evidence. Appendix 3 includes a summary of the key observational and case studies among humans that comprise the main body of evidence.

These nPEP guidelines are not applicable for occupational exposures to HIV; however, we attempted to standardize the selection of preferred drugs for nPEP and occupational postexposure prophylaxis (oPEP).[2] These guidelines also do not apply to continuous daily oral antiretroviral prophylaxis that is initiated before potential exposures to HIV as a means of reducing the risk for HIV infection among persons at high risk for its sexual acquisition (preexposure prophylaxis or PrEP[11]).

Among the limitations of these guidelines is that they are based on a historical case-control study related to occupational PEP among hospital workers, observational and case studies examining nPEP's effectiveness among humans, animal studies related to PEP's efficacy among primates, and expert opinion on clinical practice among humans related to nPEP. Because of concerns about the ethics and feasibility of conducting large-scale prospective randomized placebo-controlled nPEP clinical trials, no such studies have been

conducted. Additionally, although nPEP failures were rare in the observational studies we reviewed, those studies often have inadequate follow-up testing rates for HIV infection; therefore, nPEP failures might be underestimated. Because these guidelines represent an update of previous guidelines about a now established clinical practice, we elected not to use a formal grading scheme to indicate the strength of supporting evidence.

VI. Evidence Review

VI-A. Possible Effectiveness of nPEP

No randomized, placebo-controlled clinical trial of nPEP has been conducted. However, data relevant to nPEP guidelines are available from animal transmission models, perinatal clinical trials, observational studies of health care workers receiving prophylaxis after occupational exposures, and observational and case studies of nPEP use. Although the working group mainly systematically reviewed studies conducted after 2005 through July 2015, we also include findings from seminal studies published before 2005 that help define key aspects of nPEP guidelines. Newer data reviewed in this document continue to support the assertion that nPEP initiated soon after exposure and continued for 28 days with sufficient medication adherence can reduce the risk for acquiring HIV infection after nonoccupational exposures.

V1-A1. oPEP Studies

A case-control study demonstrating an 81% (95% confidence interval [CI] = 48%–94%) reduction in the odds of HIV transmission among health care workers with percutaneous exposure to HIV who received zidovudine (ZDV) prophylaxis was the first to describe the efficacy of oPEP.[12] Because of the ethical and operational challenges, no randomized controlled trials have been conducted to test the efficacy of nPEP directly. In the absence of a randomized controlled trial for nPEP, this case-control study reports the strongest evidence of benefit of antiretroviral prophylaxis initiated after HIV exposure among humans.

V1-A2. Observational and Case Studies of nPEP

The following is a synopsis of domestic and international observational studies and case reports that have been published since the 2005 U.S. nPEP guidelines were issued. In the majority of studies, failure of nPEP, defined as HIV seroconversion despite taking nPEP as recommended, was typically confirmed by a seronegative HIV enzyme-linked immunosorbent assay (ELISA) at baseline visit, followed by a positive ELISA and Western blot or indirect fluorescent antibody (IFA) during a follow-up visit.

VI-A2a. Men Who Have Sex with Men

Based on 1 case report[13] and 6 studies[14-19] reporting results exclusively or separately among men who have sex with men (MSM), 49 seroconversions were reported after nPEP use. The case report from Italy described an nPEP failure in an MSM despite self-reported 100% adherence to his 3-drug medication regimen consisting of ZDV, lamivudine (3TC), and indinavir (IDV) and denial of ongoing HIV risk transmission behaviors after completing nPEP; concomitant hepatitis C virus (HCV) seroconversion was also diagnosed.[13] In the 6 studies, 48 of 1,535 (31.3 seroconverions/1,000 persons) MSM participants became HIV infected despite nPEP use. At least 40 of the 48 seroconversions likely resulted from ongoing risk behavior after completing nPEP. Thirty-five of these 40 seroconversions occurred ≥ 180 days subsequent to nPEP initiation and are unlikely to constitute nPEP failures.[16,18] The remaining 8 seroconverters among 1,535 MSM participants (5.2 seroconverions/1,000 persons) may be classified as potential nPEP failures. This included 1 recipient with an indeterminate HIV test result and isolation of an M184 mutation resistant virus on the last day of his 28-day regimen despite initiating

nPEP ≤ 48 hours after exposure,[20] indicating that seroconversion was occurring during the 28-day period of nPEP administration. Another 4 patients seroconverted at 91 days, 133 days, 160 days, and 168 days after nPEP initiation, including 3 who reported completing the 28-day regimen; however, there was no description of the presence or lack of ongoing sexual risk behaviors after nPEP completion.[18] Among the remaining 3 men who seroconverted after taking nPEP, taking nPEP was not associated with any suggestion of change in seroconversion risk, although no information was reported regarding the nPEP regimen prescribed, adherence to nPEP, delay in nPEP initiation or timing of HIV-positive results.[15]

In a 2-year prospective study in Brazil, investigators provided 200 seronegative MSM at high risk with education regarding nPEP and a 4-day starter pack with instructions to initiate its use for a suspected eligible exposure.[16] A follow-up 24-day pack (to complete a 28-day course) was provided only for those men with eligible exposures. Sixty-eight of 200 MSM initiated nPEP. Adherence to nPEP medications was estimated on the basis of questions at the 28-day visit and remaining pill counts. The entire 28-day nPEP regimen was completed by 89% of men with eligible exposures including 1 participant who seroconverted. Ten of 11 seroconversions occurred among men who did not initiate nPEP.[16]

VI-A2b. Sexual Assault

VI-A2bi. General Population (all ages). Globally, 3 systematic reviews[20-22] and 1 prospective *cohort* study[23] spanning childhood through adulthood reported wide-ranging proportions of participants being eligible for nPEP (range, 6%–94%), being offered nPEP (range, 5%–94%), accepting nPEP (range, 4%–100%), or completing nPEP (range, 9%–65%). Among the 3 systematic reviews, none reported HIV screening results or the number of nPEP failures.[20-22]

VI-A2bii. Adults and Adolescents. Although nPEP use for sexual assault survivors has been widely encouraged both in the United States and elsewhere,[24-27] documented cases of HIV infection resulting from sexual assault of women or men rarely have been published.[25,28,29] Of 5 individual retrospective studies of nPEP limited to adult and/or adolescent sexual assault survivors that the working group reviewed, 3 reported no seroconversions at baseline or at follow-up among those sexual assault survivors who completed nPEP,[30-32] and 2 did not report any information about HIV screening results or the number of nPEP failures.[33,34]

VI-A2biii. Children and Adolescents. Studies of nPEP also have focused on children or adolescents evaluated for sexual assault. In a pooled analysis based on 10 studies of 8,336 children or adolescents evaluated for sexual assault or abuse, at least 1,362 were determined to be nPEP eligible. Twenty-four of the remaining 6,974 (3.4 seroconversions/1,000 persons) children or adolescents who were not eligible for nPEP were found to be HIV infected at baseline testing.[35-44] Among 672 children or adolescents reported to have been offered nPEP, 472 were known to have initiated nPEP, and 126 were reported to have completed a 28-day nPEP course. No new HIV infections were documented among these 472 (0.0 seroconversions/1,000 persons) children/adolescents in the pooled analysis who initiated nPEP. New HIV infections might have been underestimated as return rates for children or adolescents attending at least 1 follow-up visit during which an HIV test might have been conducted after initiating nPEP ranged from 10%[40] to 76%.[44]

VI-A2c. Mixed or Other Populations

VI-A2ci. Mixed populations. Eighteen studies, including 9 international studies[45-54] and 9 domestic studies[55-63] examined multiple routes of HIV risk exposure among adults, adolescents, and children with sexual and nonsexual exposures, including consensual sexual relations, sexual assault, injection drug use, and needlestick exposures.

Fifteen of the 19 studies reported both the number of participants who completed 28 days of nPEP and the number of participants who HIV seroconverted after initiating nPEP.[46-58,62,63] In these 15 studies, 2,209 participants completed 28 days of nPEP, of whom, at least 19 individuals HIV seroconverted,[45-48,52,54,56,62,63] but

only 1 seroconversion[47] (8.6/1,000) was attributed to nPEP failure. This seroconversion occurred 6 weeks after nPEP initiation in a sexually assaulted female who presented ≤ 4 hours after assault and completed nPEP.[47] She had a positive HIV RNA polymerase chain reaction (PCR) test but no confirmatory HIV ELISA test documented during the 5–6 week follow-up HIV testing period after initiating nPEP. Among the other 18 seroconversions that occurred during follow-up HIV testing among participants who completed 28 days of nPEP, 5 occurred ≥6 months after nPEP completion and were likely associated with ongoing sexual risk behavior after nPEP completion.[45,54] One seroconversion occurred after a participant reported poor adherence to nPEP, ongoing sexual risk behavior, and multiple nPEP courses after the initial course of nPEP, however, the timing of seroconversion was not clearly specified.[63] One seroconversion occurred in an MSM presenting with acute retroviral syndrome 3 weeks after condomless anal sex with an anonymous partner and no receipt of nPEP.[48] One seroconversion occurred in a woman during the 6-month follow-up period after completing nPEP and it was attributed to ongoing sharing of injection drug use equipment.[48] One seroconversion occurred in a patient who started nPEP > 72 hours after a high-risk exposure.[46] Additional seroconversions occurred at various time periods after initiation of nPEP without detailed information about ongoing sexual exposure or adherence to nPEP (2 and 5 months [n=2 participants][62]; 3 and 6 months [n=2 participants][52]; 5 months [n=1 participant][62]; and 12 months [n=1 participant]).[62] Among 3 participants who seroconverted while taking or shortly after taking ZDV-containing nPEP regimens, there was a lack of information about ongoing sexual exposure or detailed information about strict adherence to the full 28-day nPEP regimen.[56] However, only 33.8%–42.1% of all patients who were administered ZDV-containing nPEP regimens in this study completed their regimens as prescribed.[56]

In the remaining 4 of 19 studies, 2 studies did not report rates of HIVseroconversion[59,60] and 2 studies did not report rates of completion of the 28-day nPEP regimen,[45,61] including a study that reported 7 seroconversions that occurred at unspecified time periods during the 6 months after nPEP initiation among 649 users of nPEP.[61]Of all nPEP clients in this study, 18.5% had previously used nPEP between 1 and 5 times.[61]

In 3 domestic studies, participants who were administered tenofovir (TDF)-containing nPEP regimens were substantially more likely than historical control subjects in studies consisting of ZDV-containing regimens to complete their prophylaxis as prescribed and less likely to experience common side effects.[49,56,57,60] In two studies, the highest completion rates were observed for the TDF-3TC (87.5%) and TDF-emtricitabine (FTC) (72.7%) arms followed by the TDF-FTC-raltegravir (RAL) (57%) and ZDV-3TC-3rd drug arms (the 3rd drug was mainly a protease inhibitor [PI]) (38.8 %).[57] In addition to the 57% of patients who completed all 3 drugs of the TDF-FTC-RAL arm, 27% of patients took their TDF-FTC and first RAL dose daily, but sometimes missed the second dose of RAL.[57] In another study, the completion rates were highest in the TDF-FTC-ritonavir (RTV)-boosted lopinavir (LPV/r) arm (88.3%) compared with the TDF-3TC-RTV-boosted atazanavir (ATV/r) arm (79%), ZDV-3TC-LPV/r arm (77.5%), or ZDV-3TC-nelfinavir (NFV) arm (65.5%).[49] In the last domestic study, TDF-containing compared with ZDV-containing regimens were associated with significantly higher completion rates in the bivariate analysis (OR 2.80 [95% CI = 1.69–1.18]) but not in the multivariate analysis (OR 1.96 [95% CI = 0.73–5.28]).[60]

VI-A2cii. Other Populations. Data for 438 persons with unintentional nonoccupational needlestick or other sharps exposures described in 7 published reports were reviewed, including data for 417 children and 21 adults.[64-70] Childhood and adolescent exposures were characterized as community-acquired exposures occurring in public outdoor places (e.g., playgrounds, parks, or beaches) or by reaching into needle disposal boxes at home or in a hospital. Adult exposures were often similar to occupational exposures occurring while handling needles or disposing of needles in a sharps container. In all cases, the HIV status of the source person was unknown except in 1 report[64] involving multiple percutaneous exposures with lancets among 21 children while playing with discarded needles in a playground. Some of the lancets had been used multiple times to stick different children. One of the children stuck with a lancet was known to be HIV infected before the incident, not receiving antiretroviral therapy, and documented to have an HIV-1 plasma viral load of 5,250,000 copies/mL; the other 20 children were considered potentially exposed to HIV.[64] Additionally, in 1 of the studies, 2 children

were hepatitis B surface antigen (HBsAg)-positive at baseline before starting prophylaxis.[66] Among 155 children offered nPEP, 149 accepted and initiated nPEP, and 93 completed their 28-day nPEP course.[64-70] Antiretroviral prophylaxis with either ZDV and 3TC or ZDV, 3TC plus a PI (IDV, NFV, LPV/r) or a non-nucleoside reverse transcriptase inhibitor (NNRTI) (nevirapine [NVP]) was used for those 149 children or adults accepting and initiating nPEP. No seroconversions for HIV, hepatitis B virus (HBV), or HCV were reported among those receiving or not receiving nPEP.[64-70]

In the case report of a 12-year old girl in Saudi Arabia with sickle-cell disease who was inadvertently transfused with a large volume of packed red blood cells, the use of a 13-week, 4-drug nPEP regimen of TDF, FTC, ritonavir-boosted darunavir (DRV/r) (later changed to LPV) and RAL resulted in loss of presence of detectable HIV-1 antibodies.[71] No HIV-1 DNA or plasma HIV-1 RNA was detected by PCR testing during the 8-month follow-up period.

VI-A3. Postnatal Prophylaxis of Infants Born to HIV-infected Mothers

Data regarding the efficacy of infant PEP to prevent mother-to-child HIV transmission provides only limited, indirect information about the efficacy of antiretroviral medications for nPEP. Postpartum antiretroviral prophylaxis is designed to prevent infection after contact of mucosal surfaces (ocular, oral, rectal, or urethral) or broken skin in the infant with maternal blood or other fluids that are present at time of labor and delivery, especially during vaginal births. Trials in which the infant was provided postpartum prophylaxis but the mother received neither prepartum or intrapartum antiretroviral prophylaxis provide the most relevant indirect data regarding nPEP after exposure to a source who did not have suppressed viral load secondary to antiretroviral therapy. Although a combination of prophylaxis during the prenatal, intrapartum, and postpartum periods offers the most effective reduction of perinatal transmission, postpartum prophylaxis alone also offers reduction.[72-75]

A randomized open-label clinical trial of antiretrovirals provided to infants born to breastfeeding HIV-infected women demonstrated an overall reduction in postnatal HIV infection at 14 weeks (the end of the period of prophylaxis) by approximately 70% (95% CI unreported). The trial compared a control group receiving a short-arm postnatal prophylaxis regimen and 2 comparison groups, each receiving different extended-arm postnatal prophylaxis regimens.[76] The control group received the short-arm regimen consisting of single-dose NVP plus 1-week ZDV and the 2 comparison groups received the control regimen and either 1) extended daily NVP for 14 weeks or 2) extended daily NVP and ZDV for 14 weeks. The corresponding HIV infection rates at 14 weeks were 8.5% in the control group, and 2.6% and 2.5% in the 2 extended arms comparison groups, respectively.

An observational study documented a potential effect of ZDV prophylaxis initially started postnatally compared with the prepartum and intrapartum periods. A review of 939 medical records of HIV-exposed infants in New York State indicated that the later the prophylaxis was started after the prepartum period, the higher the likelihood of perinatal transmission and that a benefit existed to postnatal prophylaxis alone (without maternal intrapartum or prepartum medication). Perinatal prophylaxis started during the prepartum, intrapartum, early postpartum (≤48 hours after birth), and late postpartum (3 days–42 days) periods resulted in corresponding transmission rates of 6.1%, 10.0%, 9.3%, and 18.4%, respectively.[77] A perinatal transmission rate of 31.6% was observed when no perinatal prophylaxis was provided; the study included data from patients who had pregnancies early in the epidemic when HIV perinatal prophylaxis was first being implemented, and it was uncertain whether using intrapartum and/or postnatal prophylaxis alone was beneficial among mothers without prenatal care.

VI-A4. Animal Studies

Macaque models have been used to assess potential PEP efficacy. These studies examined artificial exposures to simian immunodeficiency virus (SIV) which varied by modes of exposure, virus innocula, and drug

regimens. The parameters imposed by those animal studies might not reflect human viral exposures and drug exposures, and those differences should be considered when interpreting their findings. Nevertheless, macaque models have provided important proof-of-concept data regarding PEP efficacy. More recent animal studies have tested the effectiveness of newer antiretrovirals and alternate routes of PEP administration. Subcutaneous tenofovir was reported to block SIV infection after intravenous challenge among long-tailed macaques if initiated ≤ 24 hours after exposure and continued for 28 days.[78] All 10 macaques initiated on PEP at 4 or 24 hours post inoculation were documented to be SIV-uninfected at 36–56 weeks post inoculation compared with all 10 macaques that failed to receive any prophylaxis and became SIV infected within 20–36 weeks post-inoculation. In a study of 24 macaques, TDF was less effective if initiated 48 or 72 hours post-exposure or if continued for only 3 or 10 days.[79] In contrast, all 11 macaques became SIV infected in a study involving 3 control macaques receiving no prophylaxis and 8 macaques receiving a combination of ZDV, 3TC, and IDV administered orally through nasogastric catheter after intravenous virus inoculation at 4 or 72 hours post-SIV inoculation.[80] High virus innocula and drug exposures that are lower than those achieved among humans as a result of inadequate interspecies adjustment of drug dosing might have contributed to the lack of protection reported for that study. However, a macaque study designed to model nPEP for vaginal HIV exposure demonstrated that a combination of ZDV, 3TC and a high dose of IDV protected 4 of 6 animals from vaginal SIV infection when initiated ≤ 4 hours after vaginal exposure and continued for 28 days, whereas 6 of 6 animals in the control group receiving a placebo became SIV infected.[81] In another study, after 20 vaginal simian/human immunodeficiency virus infection (SHIV) challenges and a 10-week follow-up period, 5 of 6 macaques were protected when treated with topically applied gel containing 1% RAL 3 hours after each virus exposure compared with none of four macaques treated with placebo gel.[82] Likewise, macaques administered subcutaneous TDF for 28 days, beginning 12 hours (4 animals) or 36 hours (4 animals) after vaginal HIV-2 exposure, were protected from infection. Three of 4 animals treated 72 hours after exposure were also protected.[83] Three of 4 untreated animals in the control group became infected with HIV-2. Overall, data from these macaque studies demonstrate that PEP might be effective among humans if initiated ≤ 72 hours and continued daily for 28 days. In a systematic review and meta-analysis of 25 nonhuman primate studies, including rhesus macaques in10 studies and cynomolgus monkeys in 5 studies, use of PEP was associated with an 89% lower risk of seroconversion compared with nonhuman primates who did not use PEP. Also, use of tenofovir compared with other drugs was associated with lower seroconversion.[84]

VI-B. Possible Risks Associated with nPEP

Concerns regarding potential risks associated with nPEP as a clinical HIV prevention intervention include the occurrence of serious adverse effects from the short-term use of antiretroviral medications by otherwise healthy persons without HIV infection, and potential selection for drug-resistant strains of virus among those who become HIV infected despite nPEP use (particularly if medication adherence is inconsistent during the 28-day course or if the source transmits resistant virus). An additional concern is that persons engaging in consensual sex or nonsterile injection drug use may rely solely on PEP instead of adopting more long-term risk-reduction behaviors such as safer sexual and drug-injecting behaviors.

VI-B1. Antiretroviral Side Effects and Toxicity

In a meta-analysis[20] of 24 nPEP-related studies, including 23 cohort studies and 1 randomized clinical trial (behavioral intervention to improve nPEP adherence), of 2,166 sexually assaulted persons, clinicians prescribed 2-drug regimens,[36,38,40,42,85-88] 3-drug regimens,[23,31,58,89-92] 2- and 3-drug regimens,[30,32,50,93,94] or an unknown number of drugs.[46,95-97] ZDV was a part of all the regimens and all 2-drug regimens contained ZDV and 3TC, except 1 study in which ZDV and zalcitabine were prescribed.[88] Antiretrovirals provided as a part of 3-drug regimens included ZDV, 3TC, NFV, IDV, LPV/r, NVP, efavirenz (EFV), or co-formulated FTC/TDF with co-formulated LPV/r. Nausea, vomiting, diarrhea, and fatigue were the most commonly reported side effects.[20]

Serious side effects have been reported occasionally (e.g., nephrolithiasis and hepatitis) in the literature.[98-100] Rarely, severe hepatotoxicity has been observed among patients administered NVP-containing regimens for both oPEP and nPEP, including a female health care worker who required a liver transplantation after taking oPEP[101]; therefore, CDC advises against use of NVP forPEP.[1,99] Also, since January 2001, product labeling for NVP states that using it as part of a PEP regimen is contraindicated.[102]

A retrospective study in western Kenya involved 296 patients who were eligible for and initiated nPEP, including 104 who completed a 28-day course of nPEP; patients received either stavudine (d4T), 3TC and NVP or ZDV, 3TC, and LPV/r.[47] Neither the proportion of patients reporting side effects (14% [LPV-containing arm] and 21% [NVP-containing arm]) nor antiretroviral therapy completion rates differed substantially between the 2 arms. The most commonly reported side effects included epigastric pain, skin rash, and nausea among patients receiving NVP-containing regimens and diarrhea, dizziness, and epigastric pain among those receiving LPV/r-containing regimens. However, 1 hepatitis-related death of a sexual assault survivor taking a NVP-containing regimen prompted investigators to change to a new PEP regimen containing ZDV, 3TC, and LPV/r. Inclusion of NVP and d4T were initially included in nPEP regimens because of availability and cost but were discontinued in 2005 as a result of adverse events and toxicities among healthy patients. This change was also influenced by a black box warning in the drug labeling for NVP describing increased toxicity among patients on NVP with higher CD4 T lymphocyte (CD4) cell counts.

Commonly used medications in the observational studies of nPEP published after 2005 included ZDV, 3TC, LPV/r, TDF, FTC, and RAL. The majority of regimens involved using 3 drugs (range, 2–4 drugs) with a daily 2-pill burden (range, 1–3 pills). The side-effect profile that included fatigue, nausea, headache, diarrhea, and other gastrointestinal complaints was similar across studies of MSM having mainly consensual sex and studies of sexual assault survivors, including mainly women, children, and a limited proportion of men.[20,23,31,44,55-57,103]

Two trials, including a total of 602 participants, compared TDF- versus ZDV-containing nPEP regimens; both reported better medication tolerability among participants taking TDF-containing regimens.[49,56] Another study reported fewer side effects among 100 adult participants prescribed a 3-drug nPEP regimen that included RAL, TDF, and TDF compared to historical controls using a 3-drug PEP regimen including ZDV, 3TC, and a RTV-boosted PI.[57]

In an open-label, nonrandomized, prospective cohort study comparing RAL-FTC-TDF in 86 MSM and FTC-TDF in 34 MSM, 92% and 91% of participants completed 28 days of treatment, respectively, with mean adherences of 89% and 90%, respectively.[17] Use of RAL rather than a PI was associated with the avoidance of 8 prescribed drug, and 37 potential illicit drug, interactions. However, in the RAL arm, 8 recipients (9%) developed mild myalgias, and 4 recipients developed grade 4 elevations in creatinine kinase. Both the myalgias and creatinine kinase elevations improved to grade 2 or less by week 4 without RAL discontinuation.

Among 100 MSM in an open-label, single-arm study at 2 public health clinics and 2 hospital EDs in urban areas in Australia, a once daily 28-day nPEP single-pill combination regimen of FTC-rilpivirine (RPV)-TDF was well tolerated with 98.5% adherence by self-report and 92% completion of the 28-day regimen.[19] However, within 1 week of completing nPEP, 1 patient developed acute abdominal pain, vomiting, and grade 4 laboratory evidence of acute pancreatitis (lipase 872 IU/L). The pancreatitis resolved $\leq$ 21 days without need for hospitalization.[19]

In a 2-arm open label randomized multicenter clinical trial in EDs in 6 urban hospitals in Barcelona, Spain, comparing ZDV/3TC + LPV/r with ZDV/3TC + atazanavir (ATV), 64% of nPEP recipients in both arms completed the 28-day course and 92% of patients reported taking > 90% of scheduled doses (without difference between arms).[53] Adverse events were reported in 46% of patients overall (49%, LPV/r arm; 43%, ATV arm). Gastrointestinal problems were more common in the LPV/r arm.

A pooled series of case reports revealed that 142 (67%; range, 0%–99%) of 213 children and adolescents who initiated nPEP and who had ≥1 follow-up visit, reported adverse effects and 139 of 465 (30%; range, 0%–64.7%) children and adolescents who initiated nPEP, completed their course of nPEP.[32,35-44] Most commonly reported nPEP regimens included ZDV + 3TC or ZDV + 3TC + (NFV or IDV or LPV/r). Most common adverse events among the 213 participants included nausea (n = 83; 39%), fatigue (n = 58; 27%), vomiting (n = 38; 18%), headache (n = 26; 12%), diarrhea (n = 25; 12%), and abdominal pain (n = 15; 7%).

V1-B2. Selection of Resistant Virus

In instances where nPEP fails to prevent infection, selection of resistant virus by the antiretroviral drugs is theoretically possible. However, because of the paucity of resistance testing in documented nPEP failures, the likelihood of resistance occurring is unknown.

A case report from Brazil documented a 3TC-resistance mutation on day 28 of therapy in a man treated with ZDV and 3TC who subsequently underwent HIV seroconversion.[16] Although the patient was noted to have taken nPEP, detailed information regarding adherence was unreported. Because the source-person could not be tested, whether the mutation was present at the time of transmission or whether it emerged during nPEP use is unknown.

Rationale for the concern regarding acquiring resistant virus from the exposure that leads to nPEP prescription includes data from an international meta-analysis of 287 published studies of transmitted HIV-1 drug resistance among 50,870 individuals during March 1, 2000–December 31, 2013, including 27 studies and 9,283 individuals from North America.[104] The study-level estimate of transmitted drug resistance in North America was 11.5% (resistance to any antiretroviral drug class), 5.8% (resistance to NRTIs), 4.5% (resistance to NNRTIs, and 3.0% (resistance to PIs).

VI-B3. Effects of nPEP on Risk Behaviors

The majority of studies examining the association between use and availability of nPEP and sexual risk behaviors during or after its use have been conducted in developed countries, primarily among MSM; no studies related to risk compensation were conducted among persons with injection-related risk factors.[14,16,105-111] The majority of these studies did not report increases in high-risk sexual behaviors after receipt of nPEP[14,16,106,110,111] and participants sometimes reported a decrease in sexual risk-taking behavior.[16,106] However, in 3 studies, nPEP users were more likely than persons who did not use nPEP to report having multiple partners and engaging in condomless receptive or insertive anal sex with HIV-infected partners or partners with unknown serostatus after completing nPEP.[14,108,110] In 2 of these studies, nPEP users were also more likely to subsequently become HIV infected than patients who did not use nPEP.[108,110] During 2000–2009 in the Amsterdam Cohort Study, MSM who were prescribed nPEP, compared with a reference cohort of MSM, had an incidence of HIV infection approximately 4 times as high (6.4 versus 1.6/100 person-years).[108] During 2001–2007, MSM in a community cohort study in Sydney, Australia reported continued, but not increased, high-risk sexual behaviors among nPEP users; more specifically, no change in sexual behavior was reported at 6 months after 154 incident nPEP uses and after ≥18 months for 89 incident nPEP uses. Among those MSM who received nPEP, the hazard ratio of subsequent HIV infection was 2.67 (95% CI = 1.40, 5.08).[110] The authors did not attribute this elevated risk for HIV seroconversion among users of nPEP to nPEP failure but rather to a documented higher prevalence of condomless anal intercourse (CAI) with HIV-infected partners among users of nPEP, compared with persons who did not use nPEP. In summary, users of nPEP, compared with participants who did not use nPEP had a continued higher prevalence of ongoing CAI with HIV-infected persons resulting in a greater likelihood of HIV seroconversion during all periods, especially after completing nPEP. In another study, repeated courses of nPEP were unassociated with risk for subsequent HIV infection.[45] In a study of 99 patients who attended a clinic in Toronto to be evaluated for nPEP during January 1, 2013–September 30, 2014, 31 (31%) met CDC criteria for

PrEP initiation.[112] PrEP candidacy in this study was associated with sexual exposure to HIV, prior nPEP use, and lack of drug insurance. Those studies[14,108,110,112] demonstrate that certain nPEP users with ongoing high-risk sexual behaviors might need additional behavioral and biomedical prevention interventions, including PrEP, instead of nPEP.[11,113]

One U.S.-based study among 89 MSM that examined risk behavior during the 28-day course of nPEP reported that among participants, 21% reported having insertive or receptive CAI, and 43% reported engaging with ≥ 1 partner known to be HIV-positive or of unknown serostatus (i.e., a high-risk partner).[105] Ninety-four percent of participants reporting having high-risk partners also reported having insertive or receptive anal intercourse. Of participants with high-risk partners and who practiced insertive or receptive anal intercourse, 26% reported CAI with their high-risk partner while receiving nPEP. The strongest predictor of CAI during nPEP in that study was HIV engagement, defined as receiving services from an HIV-related organization, donating money to or volunteering for an HIV-related cause, or reading HIV-related magazines and online sites. A nearly 5-fold chance of reporting condomless sex with a high-risk partner during nPEP was associated with each standard deviation increase in HIV engagement (OR 4.7 [95% CI = 1.3–17.04]). Investigators hypothesized that persons who are more involved with HIV-related services or organizations might be more informed about the effectiveness of nPEP and more likely to perceive themselves to be at less risk for HIV transmission while receiving nPEP and therefore more likely to have CAI.[105]

Awareness of nPEP availability, defined as general knowledge of availability of nPEP as a tool for preventing HIV infection after a potential HIV exposure[107] or nPEP use more than once in 5 years,[103] was associated with condomless sex among MSM.[103,107] Additionally, a longitudinal study of MSM in the Netherlands reported no associations existed between any nPEP-related beliefs (e.g., perceiving less HIV or acquired immunodeficiency syndrome (AIDS) threat, given the availability of nPEP, or perceiving high effectiveness of nPEP in preventing HIV) and the incidence of sexually transmitted infections (STIs) or new HIV infection.[109]

VI-C. Antiretroviral Use During Pregnancy

No trials have been conducted to evaluate use or the maternal or fetal health effects of short-term (i.e., 28-day) antiretroviral use as nPEP among pregnant women without HIV infection. However, clinical trials have been conducted and extensive observational data exist regarding use of specific antiretrovirals during pregnancy among HIV-infected women both when initiated as treatment for health benefits to the women and when initiated to reduce mother-to-child HIV transmission. Although duration of antiretroviral use during pregnancy has varied in these trials, it often spans months of pregnancy. Only ZDV is specifically approved for use in pregnancy, but as a result of data from clinical trials, other antiretroviral drugs have been reported to have short-term safety for pregnant women and their fetuses, and therefore can be considered for nPEP in women who are or who might become pregnant. See *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States* for information regarding use of specific antiretrovirals during pregnancy.[114] Additionally, results from ongoing surveillance of major teratogenic effects related to antiretroviral use during pregnancy are described in the Antiretroviral Pregnancy Registry International Interim Report every 6 months.[115]

Certain antiretrovirals have been associated with severe side effects, toxicity, potential for teratogenicity, or other untoward effects among pregnant and non-pregnant women with HIV infection[114] and therefore are not recommended for nPEP use (see section VII-F2b. Pregnant Women and Women of Childbearing Potential for a list of antiretroviral medications that should not be used for nPEP in pregnant women). These include EFV, NVP, and d4T plus didanosine (DDI).[114] Using IDV without RTV-boosting demonstrated altered drug metabolism during pregnancy.[116,117] No severe side effects, toxicity, or adverse pregnancy outcomes have been reported to occur among HIV-uninfected women taking antiretrovirals for oPEP or nPEP.

Reports are conflicting regarding whether an association exists of substantial malformations with use of EFV during the first trimester among humans. Studies using cynomolgus monkeys reported a potential association between neurologic congenital malformations and first-trimester use of EFV.[118] Although case reports exist of neurologic defects among infants of women receiving EFV,[119,120] no elevated risk for overall congenital malformations associated with first-trimester EFV exposure have been reported in either prospectively reported pregnancies from the Antiretroviral Pregnancy Registry[115] or from a meta-analysis of 23 studies with birth outcomes from 2,026 live births among women receiving EFV during the first trimester.[121]

HIV-infected pregnant women receiving combination antiretroviral regimens that included NVP have been reported to suffer severe hepatic adverse events, including death. However, whether pregnancy increases the risk for hepatotoxic events associated with NVP therapy is unknown. Use of NVP in HIV-infected women (regardless of pregnancy status) with high CD4 counts >250 cells/mm^3[102] or elevated transaminase levels at baseline[122] has been associated with potentially life-threatening rash and hepatotoxicity. NVP use in 3 HIV-infected women with CD4 counts <100 cells/mm^3 at baseline has been associated with death among those also taking anti-tuberculosis therapy.[122]

Among antiretroviral medication combinations no longer recommended, regimens containing d4T with DDI have been associated with severe maternal lactic acidosis among pregnant HIV-infected women,[123,124] including severe necrotic pancreatic and hepatic steatosis and necrotic cellulitis of the abdominal wall in 1 woman,[123] 1 fetal demise (normal for gestational age) at 38 weeks gestation,[124] and 1 postnatal death at age 2 weeks in a 1,000 gram infant with trisomy 18.[123] Additionally, using IDV without RTV-boosting during pregnancy results in substantially lower antepartum exposures of IDV, compared with use of RTV-boosted IDV.[116,117]

VI-D. Behavioral Intervention to Support Risk Reduction During nPEP Use

Study findings from 2 randomized control trials underscore the importance of combining nPEP with behavioral interventions[125] to support continuing risk reduction. In a randomized controlled counseling intervention trial among nPEP recipients at a single U.S. site, investigators compared behavioral effects among those who received 2 (standard) versus 5 (enhanced) risk-reduction counseling sessions. Both interventions were based on social cognitive theory, motivational interviewing, and coping effectiveness. Compared with baseline, a reduction occurred at 12 months in the reported number of condomless sex acts for both intervention arms. The group reporting ≤ 4 condomless sex acts during the previous 6 months at baseline benefitted more from the 2-session intervention, while persons reporting ≥ 5 condomless sex acts during the previous 6 months at baseline revealed a greater reduction of condomless sex acts after receiving the 5-session intervention.[126] These findings demonstrate that more counseling sessions might be necessary for persons reporting higher levels of sexual risk behavior when initiating nPEP. In another randomized control trial, MSM who received contingency management, a substance abuse intervention providing voucher-based incentives for stimulant-use abstinence, had greater nPEP completion rates, greater reductions in stimulant use, and fewer acts of condomless anal intercourse compared with control participants who received incentives that were not contingent on their substance abstinence.[127]

VI-E. Adherence to nPEP Regimens and Follow-up Visits

Difficulties in adherence have been noted in both maintaining adherence to daily doses of antiretroviral medication for 28 days among the majority of populations and adherence to follow-up clinical visits for HIV testing and other care. Such adherence difficulties appear particularly severe in studies of nPEP for sexually assaulted persons. Methods for measuring completion of nPEP medication regimen differed across studies, and loss to follow-up was a major hindrance to assessing medication adherence for the majority of studies.

In a systematic review and meta-analysis of 34 nPEP studies not including sexual assault and 26 nPEP studies including only sexual assault, nPEP completion rates were lowest among persons who experienced sexual assault (40.2% [95% CI = 31.2%, 49.2%]) and highest among persons who had other nonoccupational exposures (65.6% [95% CI = 55.6%, 75.6%]).[128] In a separate meta-analysis of 24 nPEP-related studies, including 23 cohort studies and 1 randomized behavioral intervention to improve nPEP adherence, of 2,166 sexually assaulted persons receiving nPEP and pooled across the 24 studies, 40.3% (95% CI = 32.5%–48.1%; range, 11.8%–73.9%) adhered to a 28-day course of nPEP, and 41.2% (95% CI = 31.1%–51.4%; range, 2.9%–79.7%) did not return to pick up their prescribed medication or did not return for follow-up appointments.[20] Medication adherence was measured in 24 studies by using varying methodology, including pill count, volume of syrup remaining, self-report, counts of number of pharmacy visits, recall of number of doses taken by notation on a calendar, number of prescriptions filled, and number of weekly clinic appointments kept. Reported medication adherence was lower in developed countries (n=15 studies, 5 countries)[23,30-32,36,38,46,50,58,88-92,94,97] compared with developing countries (n=8 studies, three countries)[40,42,85-87,93,95,96] (33.3% versus 53.2%, respectively; P=0.007), possibly due to higher awareness of HIV transmission risk in countries with a high HIV prevalence.[20] Eight of the 24 (33%) studies[30,32,46,86-89,97] provided nPEP medications at time of initiation of prophylaxis as starter packs including 4–7 days of medication, and 1 study provided either a starter pack of medications or a full 28-day supply of nPEP at initiation.[96] In this latter study, the proportion who adhered to the 28 days of nPEP was 29% for patients initially receiving the starter pack and 71% for patients receiving a full 28-day supply.[96]

Although sexually assaulted persons are sometimes at risk for HIV transmission, they often decline nPEP, and many who do take it do not complete the 28-day course. This pattern has been reported in multiple countries and in programs in North America. In Ontario, for example, 798 of 900 eligible sexually assaulted persons were offered nPEP, including 69 and 729 at high or unknown risk for HIV transmission due to the factors associated with their sexual assault, respectively.[23] Forty-six (67%) of 69 persons at high risk for HIV transmission and 301 (41%) of 729 persons with unknown risk accepted and initiated nPEP. Twenty-four percent of patients at high risk and 33% of patients with unknown risk completed the 28-day course. Reasons for discontinuing treatment were documented in 96 cases and included adverse effects (81%), interference with routine (42%), inability to take time away from work or school (22%), and reconsideration of HIV risk (19%).

Of the observational studies of sexually assaulted persons provided nPEP, the majority identified similar challenges. Studies have demonstrated that early discontinuation of medication and a lack of follow-up pose challenges to providing nPEP to sexually assaulted persons.[31,33,47,50]

Four international studies examined adherence among both men and women with non-assault sexual and injection drug use risk exposures.[46,48,49,51] Full medication adherence in these studies ranged from 60%–88%; 60%[48] and 79%[51] completed therapy (without specifying how completion was defined) and 67%[48] and 88%[49] completed 28 days or 4 weeks of nPEP. The proportion of MSM who adhered to nPEP medication for 28 days reported in those studies ranged from 42%–91%.

Studies that used a fixed dose combination of ZDV/3TC and LPV/r as primary components in the nPEP drug regimen reported low medication adherence for 28 days (24%–44%).[23,44,47] A study among MSM compared use of a fixed-dose combination regimen containing TDF/FTC with or without RAL (an integrase inhibitor) with ZDV/3TC and a RTV-boosted PI; adherence rates were superior for the TDF-containing regimens (57% [with RAL]–72.7% [without RAL]) compared with the PI-containing regimen (46%). Although 57% of the TDF/FTC/RAL arm reported taking their medications as directed, an additional 27% took their once daily medication, but sometimes missed their second daily dose of RAL.[57]

VI-F. nPEP Cost-effectiveness

Estimates of cost-effectiveness of nPEP as an HIV prevention method reported in the literature vary by HIV exposure route and estimated prevalence of infection among source persons. A study using data from the San Francisco nPEP program estimated the cost-effectiveness of hypothetical nPEP programs in each of the 96 metropolitan statistical areas in the United States.[129] It included 3 different data sources, including data from clinical care and drug cost data from the San Francisco Department of Public Health nPEP program,[130] estimates of the per-act probability of HIV transmission associated with different modes of sexual and parenteral HIV exposure,[131-133] and HIV prevalence data from 96 U.S. metropolitan statistical areas.[134] Investigators estimated the cost-effectiveness of hypothetical nPEP programs as an HIV prevention method in each area compared with no intervention. By defining cost-effective programs as those costing <$60,000/quality-adjusted life year (QALY), that study found nPEP programs were cost-effective across the combined metropolitan statistical areas with a cost utility ratio of $12,567/QALY saved (range, $4,147–$39,101). nPEP was most cost-effective for MSM ($4,907/QALY). It was not cost-effective for needle-sharing persons who inject drugs (PWID) ($97,867/QALY), persons sustaining nonoccupational needlesticks ($159,687/QALY), and receptive female partners ($380,891/QALY) or insertive male partners ($650,792/QALY) in penile-vaginal sex. The hypothetical nPEP program would be cost-saving (cost-utility ratio, <$0) only for men and women presenting with receptive anal intercourse or if nPEP use was limited to clients with known HIV-infected partners.[129] In another study limited to San Francisco, the overall cost-utility ratio for the existing nPEP program was $14,449/QALY saved and for men experiencing receptive anal sex, the nPEP program was cost-saving.[130]

Studies in Australia and France reported similar results. For example, in Australia, using a threshold for cost-effectiveness of $50,000/QALY, nPEP was cost-effective among persons having CAI with an HIV-infected source ($40,673/QALY).[135] In France, using thresholds for cost-saving and cost-effectiveness of €0/QALY saved and <€50,000/QALY saved, respectively, nPEP was cost-saving among men and women who had receptive anal intercourse with an HIV-infected man (-€22,141/QALY saved [men]; and -€22,031/QALY saved [women]) and cost-saving among PWID having shared needles with an HIV-infected person (-€1,141/QALY saved).[136]

Additionally, these same French and Australian studies, and a Swiss study, reported that HIV testing to determine the status of the source person (when possible) was determined to reduce costs associated with nPEP programs by avoiding unnecessary prophylaxis.[48,135,136]

VI-G. Attitudes, Policies, and Knowledge About nPEP Use Among Health Care Providers and Candidates for nPEP

Since 1997, certain health care providers, health policy makers, and scientific investigators of nPEP have recommended wider availability and/or use of nPEP,[24,131,137-144] while others have been more cautious about implementing it in the absence of definitive evidence of efficacy or effectiveness.[145,146] Multiple public health jurisdictions in the U.S., including the New York State AIDS Institute, the San Francisco County Health Department, the Massachusetts Department of Public Health, the Rhode Island Department of Health, and the California State Office of AIDS, have issued policies or advisories for nPEP use.[3,4,147,148]

Surveys of health care providers and facilities indicate a low level of awareness and capacity to provide nPEP as well as a lack of access for nPEP for those for whom it is recommended need for more widespread dissemination and implementation of guidelines and protocols for nPEP use and a need for improved access. In a study of 181 patients presenting to the emergency department (ED) who had been sexually assaulted, lack of insurance, older patient age, and acquaintance rape were factors associated with not being offered nPEP.[30] A study evaluating access to nPEP services in 117 health care sites in Los Angeles County through use of Internet

searches and telephone surveys, determined that only 14% offered nPEP to clients regardless of insurance status, and an even lower percentage, 8%, offered nPEP to uninsured clients, indicating the need to improve access to such services.[149] A survey in New York State (NYS) reported that among 184 EDs, 88% reported evaluating patients with possible nonoccupational exposures to HIV in accordance with NYS guidelines, however, full implementation of NYS nPEP guidelines was incomplete with 4% neither supplying nor prescribing antiretroviral drugs in the ED and only 22% confirming whether linkage to follow-up care was successful.[150] Screening of STIs, risk-reduction counseling, and education about symptoms of acute HIV seroconversion were not consistently performed according to the NYS guidelines.[150] Additionally, in a survey of 142 HIV health care providers in Miami and the District of Columbia, prescribing nPEP was associated with having patients request nPEP, or having a written nPEP protocol, although most providers reported not having a written nPEP protocol and that patients rarely or never requested nPEP.[151] Lack of prescribing nPEP was associated with believing that nPEP would lead to antiretroviral resistance.[151] More health care providers in the District of Columbia compared with those in Miami, prescribed nPEP (59.7% versus 39.5%, respectively $P<0.048$).[152] In a cross-sectional study describing program practices related to HIV testing and nPEP among 174 sexual assault nurse examiner (SANE)/forensic nurse examiner (FNE) programs in the U.S. and Canada, 75% had nPEP policies, 31% provided HIV testing, and 63% offered nPEP routinely or based on patient request.[153] Medication cost was the most important barrier to providing nPEP in these programs.

Awareness, knowledge, and use of nPEP has been described among MSM.[14,15,106,108,110,154] Evidence indicates awareness of nPEP and interest in its use among potential patients. When nPEP studies were established in San Francisco, approximately 400 persons sought treatment during December 1997–March 1999.[106,154] In an HIV prevention trial of 4,295 MSM in 6 U.S. cities during 1999–2003, a total of 2,037 (47%) had heard of nPEP at baseline and 315 (7%) reported using nPEP on ≥1 occasion.[14] Predictors of nPEP use included having multiple partners, engagement in condomless sex with a known HIV-infected partner or with a partner of unknown HIV status, and use of illicit drugs. Among 1,427 MSM in a community cohort of HIV-negative men in Sydney, Australia, during 2001–2007, knowledge of nPEP increased from 78.5% at baseline to 97.4% by the fifth annual interview, and nPEP use increased from 2.9/100 person-years in 2002 to 7.1/100 person-years in 2007.[110] During 2006–2009, knowledge of nPEP among MSM from urban areas in the Netherlands increased from 46% to 73%.[108] Also, the annual number of PEP prescriptions to MSM in Amsterdam increased 3-fold, from 19 in 2000 to 69 in 2007.[15]

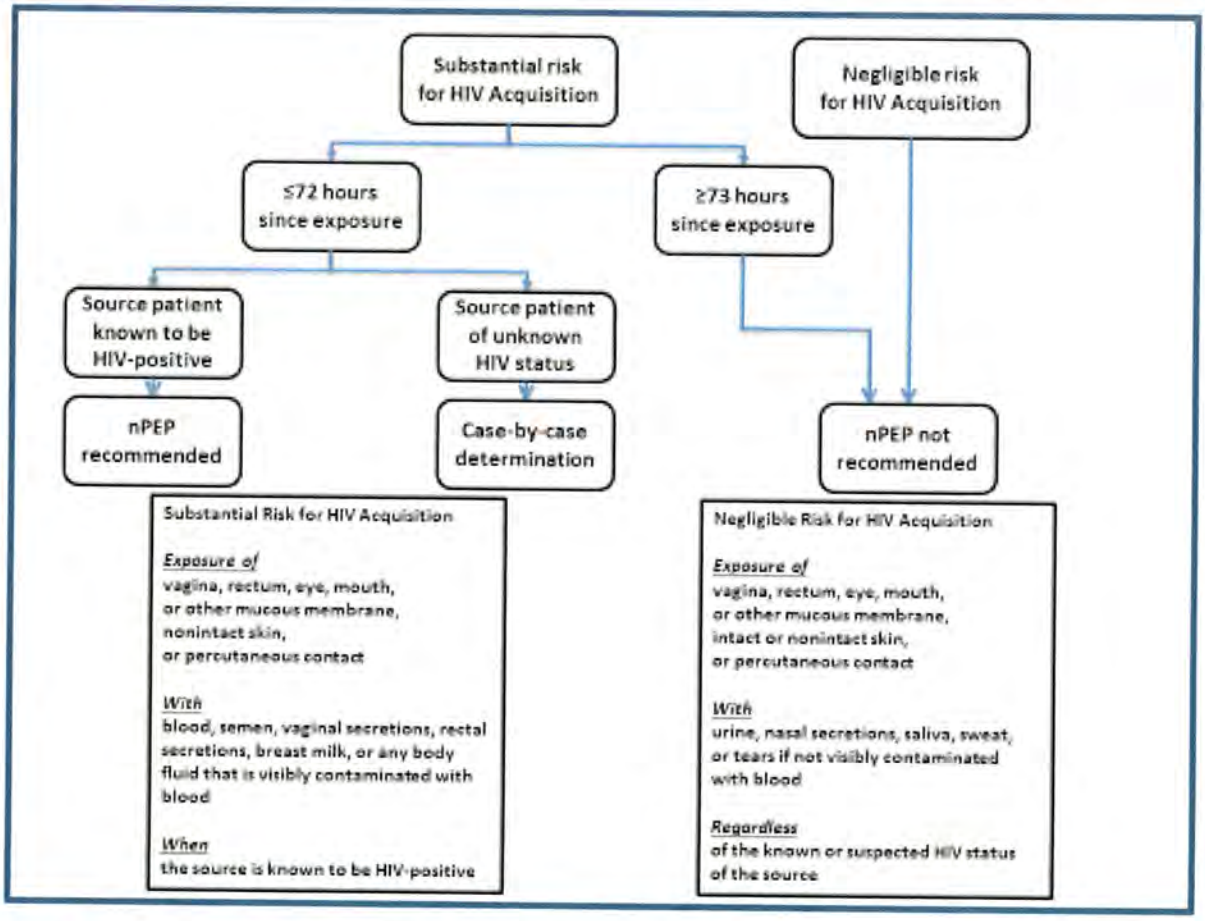
In a study of 227 pediatric and adolescent patients aged 9 months–18 years who were evaluated for sexual assault in Atlanta, Georgia, 40% of patients were examined ≤ 72 hours after the sexual assault, of whom 81% reported a history of genital or anal trauma.[41] In that study, patients aged 13–18 years and those who reported sexual assault by a stranger were more likely to present to the ED ≤ 72 hours after the sexual assault. Health care providers in the hospital's ED where this nPEP study was conducted expressed reluctance to prescribe nPEP to pre-pubertal children. For example, of 87 children and adolescents seen in the ED ≤ 72 hours after the assault, 23 had anogenital trauma or bleeding, and 5 were offered nPEP.

VII. Patient Management Guidelines

VII-A. Initial Evaluation of Persons Seeking Care After Potential Nonoccupational Exposure to HIV

Effective delivery of nPEP after exposures that carry a substantial risk for HIV infection requires prompt evaluation of patients and consideration of biomedical and behavioral interventions to address current and ongoing health risks. The initial evaluation provides the information necessary for determining if nPEP is indicated (Figure 1).

Figure 1. Algorithm for evaluation and treatment of possible nonoccupational HIV exposures



Procedures at the evaluation visit include determining the HIV infection status of the potentially exposed person and the source person (if available), the timing and characteristics of the exposure for which care is being sought, and the frequency of possible HIV exposures. Additionally, to determine whether other treatment or prophylaxis is indicated, health care providers should assess the likelihood of STIs, infections efficiently transmitted by injection practices or needlesticks (e.g., hepatitis B or hepatitis C virus), and pregnancy for women.

VII-A1. HIV Status of the Potentially Exposed Person

nPEP is only indicated for potentially exposed persons without HIV infection. Because potentially exposed persons might have acquired HIV infection already and be unaware of it, routine HIV antibody testing should

be performed on all persons seeking evaluation for potential nonoccupational HIV exposure. If possible, this should be done with an FDA-approved rapid antibody or Ag/Ab blood test kit with results available within an hour. If HIV blood test results will be unavailable during the initial evaluation visit, a decision whether nPEP is indicated should be made based on the initial assumption that the potentially exposed patient is not infected. If medication of HIV prophylaxis is indicated by the initial evaluation and started, it can be discontinued if the patient is later determined to already have HIV infection.

VII-A2. Timing and Frequency of Exposure

Available data from animal studies indicate that nPEP is most effective when initiated as soon as possible after HIV exposure; it is unlikely to be effective when instituted > 72 hours after exposure.[83] Therefore, persons should seek nPEP as soon as possible after an exposure that might confer substantial risk and health care providers should evaluate such patients rapidly and initiate nPEP promptly when indicated.

nPEP should be provided only for infrequent exposures. Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of antiretroviral medications (e.g., HIV-discordant sex partners who inconsistently use condoms or PWID who often share injection equipment) should not be prescribed frequent, repeated courses of nPEP. Instead, health care providers should provide persons with repeated HIV exposure events (or coordinate referrals for) intensive sexual or injection risk-reduction interventions, and consider the prescription of daily oral doses of the fixed-dose combination of TDF and FTC (Truvada, Gilead Sciences, Inc., Foster City, California) for PrEP.[11] However, if the most recent recurring exposure is within the 72 hours prior to an evaluation, nPEP may be indicated with transition of the patient to PrEP after completion of 28 days of nPEP medication.

In the special case of children with evidence of chronic sexual abuse who come to the attention of a health care provider ≤ 72 hours after their most recent exposure, nPEP can be considered on a case-by-case basis. In addition, child protective services should be engaged for consideration of removal of the child from exposure to the perpetrator of the sexual abuse.

VII-A3. HIV Acquisition Risk from the Exposure

In addition to determining when the potential exposure occurred, determining whether nPEP is indicated requires assessing if the reported sexual, injection drug use, or other nonoccupational exposure presents a substantial risk for HIV acquisition. Health care providers should consider 3 main factors in making that determination: (1) whether the exposure source is known to have HIV infection, (2) to which potentially infected body fluid(s) the patient was exposed, and (3) the exposure site or surface.

The highest level of risk is associated with exposure of susceptible tissues to potentially infected body fluid(s) from persons known to have HIV infection, particularly those who are not on antiretroviral treatment. Persons with exposures to potentially infectious fluids from persons of unknown HIV status are at unknown risk for acquiring HIV infection. When the source of exposure is known to be from a group with a high prevalence of HIV infection (e.g., a man who has sex with men or a PWID who shares needles or other injection equipment), the risk for unrecognized HIV infection in the source is increased.

The estimated per-act transmission risk, when exposed to infectious fluid(s) from a person with HIV infection, varies considerably by exposure route (Table 1).[155] The highest estimated per-act risks for HIV transmission are associated with blood transfusion, needle sharing during injection drug use, receptive anal intercourse, and percutaneous needlestick injuries. Insertive anal intercourse, insertive penile-vaginal intercourse, and oral sex represent substantially lower per-act transmission risk.

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act[a]

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other[b]	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

Source: http://www.cdc.gov/hiv/policies/law/risk.html

[a] Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[b] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

A history should be taken of the specific sexual, injection drug use, or other exposure events that can lead to acquiring HIV infection. Eliciting a complete description of the exposure and information about the HIV status of the partner(s) can substantially lower (e.g., if the patient was exclusively the insertive partner or a condom was used) or increase (e.g., if the partner is known to be HIV-positive) the estimate of risk for HIV transmission resulting from a specific exposure.

Percutaneous injuries from needles discarded in public settings (e.g., parks and buses) sometimes result in requests for nPEP. Although no HIV infections from such injuries have been documented, concern exists that syringes discarded by PWID might pose a substantial risk. However, such injuries typically involve small-bore needles that contain only limited amounts of blood, and the infectiousness of any virus present might be low.[156,157] Saliva that is not contaminated with blood contains HIV in much lower titers and constitutes a negligible exposure risk,[158] but saliva that is contaminated with HIV-infected blood poses a substantial exposure risk. HIV transmission by this route has been reported in ≥ 4 cases.[159-162]

VII-A4. HIV Status of the Exposure Source

When the exposure source's HIV status is unknown, that person's availability for HIV testing should be determined. When the source person is available and consents to HIV testing, a clinical evaluation visit should be arranged that includes HIV testing by using a fourth-generation combined Ag/Ab test. The risk for transmission might be especially great if the source person has been infected recently because the viral burden in blood and semen might be particularly high.[163,164] However, ascertaining this in the short time available for the initial nPEP evaluation might not be possible. If the risk associated with the exposure is high, starting nPEP and then making a decision whether to continue nPEP after the source's HIV status is determined is recommended.

If the exposure source is known to have HIV infection at the time of the nPEP evaluation visit and consents, the health care provider should attempt to interview that person or that source person's health care provider to determine the history of antiretroviral use and most recent viral load. That information might help guide the choice of nPEP medications to avoid prescribing antiretroviral medications to which the source-virus is likely to be resistant. If the person with HIV infection is willing, the clinician might consider drawing blood for viral load and resistance testing, the results of which might be useful in modifying the initial nPEP medications if the results can be obtained promptly.[165]

VII-B. Laboratory Testing

Laboratory testing is required to (1) document the HIV infection status of the person presenting for nPEP evaluation (and the exposure source when available and consent has been granted), (2) identify and clinically manage any other conditions potentially resulting from sexual- or injection-related exposure to potentially infected body fluids, (3) identify any conditions that would affect the nPEP medication regimen, and (4) monitor for safety or toxicities related to the regimen prescribed (Table 2).

Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
		For all persons considered for or prescribed nPEP for any exposure			
HIV Ag/Ab testing[a] (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓[b]
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓[c]
Hepatitis C antibody test	✓	✓	—	—	✓[d]
		For all persons considered for or prescribed nPEP for sexual exposure			
Syphilis serology[e]	✓	✓	✓	—	✓
Gonorrhea[f]	✓	✓	✓[g]	—	—
Chlamydia[f]	✓	✓	✓[g]	—	—
Pregnancy[h]	—	✓	✓	—	—
		For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance[i])		✓	✓	—	—
Alanine transaminase, aspartate aminotranferase		✓	✓	—	—
		For all persons with HIV infection confirmed at any visit			
HIV viral load	✓	✓[j]			
HIV genotypic resistance	✓	✓[j]			

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

[a] Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

[b] Only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

[c] If exposed person susceptible to hepatitis B at baseline.

[d] If exposed person susceptible to hepatitis C at baseline.

[e] If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment

[f] Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests. For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment is recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea. (http://www.cdc.gov/std/tg2015/tg-2015-print.pdf)

[g] If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

[h] If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen.

[i] eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).

[j] At first visit where determined to have HIV infection.

VII-B1. HIV Testing

All patients initiating nPEP after potential HIV exposure should be tested for the presence of HIV-1 and HIV-2 antigens and antibodies in a blood specimen at baseline (before nPEP initiation), preferably using a rapid test. Patients with baseline rapid tests indicating existing HIV infection should not be started on nPEP. Patients for whom baseline HIV rapid test results indicate no HIV infection or rapid HIV test results are not available should be offered nPEP. There should be no delay in initiation of nPEP while awaiting baseline HIV test results. Repeat HIV testing should occur at 4–6 weeks and 3 months after exposure to determine if HIV infection has occurred. See http://www.cdc.gov/hiv/testing/laboratorytests.html regarding information on approved HIV tests. Oral HIV tests are not recommended for use among persons being evaluated for nPEP.

Additionally, persons whose sexual or injection-related exposures results in concurrent acquisition of HCV and HIV infection might have delayed HIV seroconversion. This has been documented among MSM with sexual exposure[13] and health care personnel receiving oPEP for needlestick exposures.[166,167] Therefore, for any person whose HCV antibody test is negative at baseline but positive at 4–6 weeks after the exposure, HIV antibody tests should be conducted at 3 and 6 months to rule out delayed seroconversion (see Table 2).

VII-B2. Recognizing Acute HIV Infection at Time of HIV Seroconversion

Persons initiating nPEP, if it fails, may experience signs and symptoms of acute HIV infection while on nPEP. At the initial visit, patients should be instructed about the signs and symptoms associated with acute (primary) HIV infection (Table 3), especially fever and rash,[168] and asked to return for evaluation if these occur during the 28 days of prophylaxis or anytime within a month after nPEP concludes.

Table 3. Clinical signs and symptoms of acute (primary) human immunodeficiency virus infection[169,170]

		Sex		Mode of HIV acquisition	
Features	**Overall (n=375), %**	**Male (n=355), %**	**Female (n=23), %**	**Sexual (n=324), %**	**Injection drug use (n=34), %**
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

Acute HIV infection is associated with high viral load. However, health care providers should be aware that available assays might yield low viral-load results (e.g., <3,000 copies/ml) among persons without HIV infection (i.e., false-positives). Without confirmatory tests, such false-positive results can lead to misdiagnoses of HIV infection.[171] Transient, low-grade viremia has been observed among persons exposed to HIV who were

administered antiretroviral nPEP[172] and did not become infected. In certain cases, this outcome might represent aborted infection rather than false-positive test results, but this can be determined only through further testing.

All patients who have begun taking nPEP and for whom laboratory evidence later confirms acute HIV infection at baseline or whose follow-up antibody testing indicates HIV infection, should be transferred rapidly to the care of an HIV treatment specialist (if nPEP was provided by another type of health care provider). If the patient is taking a 3-drug antiretroviral regimen for nPEP at the time of HIV infection diagnosis, the 3-drug regimen should not be discontinued by the nPEP provider until the patient has been evaluated and a treatment plan initiated by an experienced HIV care provider.[173]

VII-B3. STI Testing

Any sexual exposure that presents a risk for HIV infection might also place a person at risk for acquiring other STIs.[174] For all persons evaluated for nPEP because of exposure during sexual encounters, STI-specific nucleic acid amplification (NAAT) testing is recommended for gonorrhea and chlamydia,[174] by testing first-catch urine or with swabs collected from each mucosal site exposed to potentially infected body fluids (oral, vaginal, cervical, urethral, rectal).[174,175] Additionally, blood tests for syphilis should be conducted for all persons evaluated for nPEP.

VII-B4. HBV Testing

HBV infection is of specific concern when considering nPEP for 2 reasons. First, multiple medications used for nPEP, including 2 in the preferred regimen (TDF and FTC) are active against HBV infection. For safety reasons, health care providers need to know if a patient has active HBV infection (positive hepatitis B surface antigen [HBsAg]) so that the patient can be closely monitored for reactivation "flare ups" when nPEP is stopped, and treatment for HBV infection is discontinued. Although this is rare, it can result in substantial hepatic dysfunction if not detected and treated early. Additionally, obtaining hepatitis serology (HBsAg, hepatitis B surface antibody [anti-HBs], and hepatitis B core antibody [anti-HBc]) will identify nonimmune persons who should be provided hepatitis B vaccination Table 4).[176]

Table 4. Hepatitis B virus screening serology[177]

HBsAg	Anti-HBc	Anti-HBs	IgM Anti-HBc	Interpretation	Action
Negative	Negative	Negative	—	Susceptible	Vaccinate
Negative	Positive	Positive	—	Immune (natural infection)	Document
Negative	Negative	Positive	—	Immune (prior vaccination)	Document
Positive	Positive	Negative	Negative	Chronic hepatitis B virus infection	Evaluate for treatment
Positive	Positive	Negative	Positive	Acute hepatitis B virus infection	Follow and evaluate for treatment
Negative	Positive	Negative	—	Unclear—might be: • resolved infection (most common) • false-positive anti-HBc; susceptible • "low level" chronic infection • resolving acute infection	Case-by-case evaluation

Abbreviations: HBsAg, hepatitis B surface antigen; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody.

VII-B5. Pregnancy Testing

nPEP is not contraindicated for pregnant women. Moreover, because pregnancy has been demonstrated to increase susceptibility to sexual HIV acquisition,[178] nPEP can be especially important for women who are pregnant at the time of sexual HIV exposure.

For women of reproductive capacity who have had genital exposure to semen and a negative pregnancy test when evaluated for possible nPEP, current contraception use should be assessed, and if a risk for pregnancy exists, emergency contraception should be discussed with the patient.

VII-B6. Baseline and Follow-up Testing to Assess Safety of Antiretroviral Use for nPEP

All patients who will be prescribed nPEP should have serum creatinine measured and an estimated creatinine clearance calculated at baseline to guide selection of a safe and appropriate antiretroviral regimen for nPEP. Also, health care providers treating patients with nPEP should monitor liver function, renal function, and hematologic parameters when indicated by the prescribing information for the antiretrovirals prescribed. Drug-specific recommendations are available at the online AIDS*Info* Drugs Database at: http://aidsinfo.nih.gov/drugs or the antiretroviral treatment guidelines.[114,173,179]

Unusual or severe toxicities from antiretroviral drugs should be reported to the manufacturer or FDA (http://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm, or 1-800-FDA-1088 [1-800-332-1088]).

If nPEP is prescribed to a woman who is pregnant at the time of exposure or becomes pregnant while on nPEP, health care providers should enter the patient's information (anonymously) into the Antiretroviral Pregnancy Registry (http://www.apregistry.com).

VII-C. Recommended Antiretroviral nPEP Regimens

A 28-day course of nPEP is recommended for HIV-uninfected persons who seek care ≤ 72 hours after a nonoccupational exposure to blood, genital secretions, or other potentially infected body fluids of persons known to be HIV infected or of unknown HIV status when that exposure represents a substantial risk for HIV acquisition. Since adherence is critical for nPEP efficacy, it is preferable to select regimens that minimize side effects, number of doses per day and the number of pills per dose.

No strong evidence exists, based on randomized clinical trials, that any specific combination of antiretroviral medication is optimal for nPEP use. Although a limited number of studies have evaluated the penetration of antiretroviral medications into genital tract secretions and tissues,[180-182] evidence is insufficient for recommending a specific antiretroviral medication as most effective for nPEP for sexual exposures. Therefore, the recommended regimens for nPEP in these guidelines are based on expert opinion from the accumulated experience with antiretroviral combinations that effectively suppress viral replication among HIV-infected persons for the purpose of HIV treatment and mainly observational studies of the medication tolerance and adherence when these same drugs are taken for nPEP.

The recommendation for a 3-drug antiretroviral regimen is based on extrapolation of data demonstrating that the maximal suppression of viral replication occurs among persons with HIV infection when combination antiretroviral therapy with ≥3 drugs is provided. Also, the likelihood of protection against acquiring resistant virus would be greater with a 3-drug regimen compared with a 2-drug regimen. Recommending a 3-drug regimen for all patients who receive nPEP will increase the likelihood of successful prophylaxis in light of potential exposure to virus with resistance mutation(s) and will provide consistency across PEP guidelines for

both nPEP and oPEP.[2] Additionally, if infection occurs despite nPEP, a 3-drug regimen will more likely limit emergence of resistance than a 2-drug regimen.

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP[a,b]

Age group	Preferred/ alternative	Medication
Adults and adolescents aged ≥ 13 years, including pregnant women, with normal renal function (creatinine clearance ≥ 60 mL/min)	**Preferred**	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada[c]) once daily ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg ***and*** fixed dose combination emtricitabine 200 mg (Truvada) once daily ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily
Adults and adolescents aged ≥ 13 years with renal dysfunction (creatinine clearance ≤59 mL/min)	**Preferred**	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** raltegravir 400 mg twice daily ***or*** dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine, with both doses adjusted to degree of renal function ***with*** darunavir 800 mg (as 2, 400-mg tablets) once daily ***and*** ritonavir[b] 100 mg once daily
Children aged 2–12 years	**Preferred**	A 3-drug regimen consisting of tenofovir DF, emtricitabine, and raltegravir, with each drug dosed to age and weight[d]
	Alternative	A 3-drug regimen consisting of zidovudine ***and*** lamivudine ***with*** raltegravir ***or*** lopinavir/ritonavir[b], with raltegravir and lopinavir/ritonavir dosed to age and weight[d]
	Alternative	A 3-drug regimen consisting of tenofovir DF ***and*** emtricitabine ***and*** lopinavir/ritonavir[b], with each drug dosed to age and weight[d]

Age group	Preferred/ alternative	Medication
Children aged 3–12 years	Alternative	A 3-drug regimen consisting of tenofovir DF **and** emtricitabine **and** darunavir[e]/ritonavir[b], with each drug dosed to age and weight[d]
Children aged 4 weeks[f]–< 2 years	**Preferred**	A 3-drug regimen consisting of zidovudine oral solution ***and*** lamivudine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir[b] oral solution (Kaletra[g]), with each drug dosed to age and weight[d]
Children aged 4 weeks[f]–< 2 years	Alternative	A 3-drug regimen consisting of zidovudine oral solution ***and*** emtricitabine oral solution ***with*** raltegravir ***or*** lopinavir/ritonavir[b] oral solution (Kaletra), with each drug adjusted to age and weight[d]
Children aged birth–27 days	Consult a pediatric HIV-specialist	

Abbreviations: HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

[a] These recommendations do not reflect current Food and Drug Administration-approved labeling for antiretroviral medications listed in this table.

[b] Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors. Ritonavir is not counted as a drug directly active against HIV in the above "3-drug" regimens.

[c] Gilead Sciences, Inc., Foster City, California.

[d] See also Table 6.

[e] Darunavir only FDA-approved for use among children aged ≥ 3 years.

[f] Children should have attained a postnatal age of ≥ 28 days and a postmenstrual age (i.e., first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥ 42 weeks.

[g] AbbVie, Inc., North Chicago, Illinois.

Table 6. Formulations, cautions, and dose adjustments for antiretroviral medications in preferred and alternative nPEP regimens[a]

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Tenofovir disoproxil fumarate (TDF) (Viread, Gilead Sciences, Inc., Foster City, California) Also available as component of fixed-dose combination, Truvada (Gilead Sciences, Inc., Foster City, California) (emtricitabine + TDF)	150-mg tablet 200-mg tablet 250-mg tablet 300-mg tablet 40-mg/gm powder	**Side effects:** Asthenia, headache, diarrhea, nausea, vomiting **Contraindications:** Nephrotoxicity; for nPEP, should not be administered to persons with acute or chronic kidney injury or those with eCrCl < 60 mL/min **Cautions:** TDF can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug may cause an acute hepatitis exacerbation.	**Children aged 2–11 years (powder)** • 8 mg/kg body weight • Not to exceed adult dose (300 mg qd) **Children aged 2–11 years (tablet), per body weight** • 17 to < 22 kg, 150 mg-tablet once daily • 22 to < 28 kg, 200 mg-tablet once daily • 28 to < 35 kg, 250-mg tablet once daily • ≥ 35 kg, 300-mg tablet once daily • Not to exceed adult dose (300 mg once daily)
Emtricitabine (FTC) (Emtriva, Gilead Sciences, Inc., Foster City, California) Also available as component of fixed-dose combination, Truvada (FTC + TDF)	200-mg capsule 10-mg/mL oral solution	**Side effects:** Hyperpigmented rash or skin discoloration **Cautions:** FTC can be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped because withdrawal of this drug might cause an acute hepatitis exacerbation. **Contraindications:** Do not administer with lamivudine	**Children aged 0–3 months (oral solution)** • 3 mg/kg once daily • Not to exceed 240 mg once daily **Children aged 3 months–17 years, per body weight** • 6 mg/kg once daily (oral solution) • ≥ 33 kg 200-mg tablet once daily • Not to exceed 240 mg once daily
Raltegravir (RAL) (Isentress, Merck & Co., Inc., Kenilworth, New Jersey)	400-mg tablet 100-mg chewable, scored tablet 25-mg chewable tablet	**Side effects:** Insomnia, nausea, fatigue, headache; severe skin and hypersensitivity reactions have been reported **Cautions:** Dosage adjustment required if co-administered with rifampin (800 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and certain oral multivitamins can reduce absorption of RAL. RAL should be administered ≥ 2 hours before or ≥ 6 hours after administration of cation-containing medications or products, however, RAL can be co-administered with calcium carbonate-containing antacids.[154] **Contraindications:** None	**Children aged 6–12 years and weighing > 25 kg** • 400 mg-tablet twice daily **Or** • Chewable tablets twice daily. See table below for chewable tablet dose. **Children aged 2–12 years (chewable tablets), per body weight** • 11 to < 14 kg, 75-mg twice daily • 14 to < 20 kg, 100-mg twice daily • 20 to < 28 kg, 150-mg twice daily • 28 to < 40 kg, 200-mg twice daily • ≥ 40 kg, 300-mg twice daily

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Dolutegravir (DTG) (Tivicay, ViiV Healthcare, Brentford, Middlesex, United Kingdom)	50-mg tablet	**Side effects:** Insomnia, headache **Cautions:** Dosage adjustment required if co-administered with rifampin, fosamprenavir/ritonavir, tipranvir/ritonavir, or efavirenz (50 mg twice daily for adults). Co-administration with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and some oral multivitamins can reduce absorption of DTG. DTG should be administered ≥2 hours before or at ≥6 hours after administration of cation-containing medications or products.[151] **Contraindications:** Do not administer with dofetilide.	**Children aged 12 years old and older and weighing ≥40 kg** • 50-mg tablet once daily
Darunavir (DRV)/ritonavir(RTV) (Prezista, Janssen Therapeutics, Titusville, New Jersey)	75-mg tablet 150-mg tablet 400-mg tablet 600-mg tablet 100-mg/mL oral suspension	**Side effects:** Rash (sulfonamide allergy), diarrhea, nausea, headache **Cautions:** Must be administered with food; must be co-administered with ritonavir; can cause hepatotoxicity. Use with caution with persons with known allergy to sulfonamide medications **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life-threatening adverse events.	**Children aged 3 to < 18 years and weight > 10 kg** WEIGHT (KG) — DOSE (TWICE DAILY WITH FOOD) 10 to < 11 kg* — darunavir 200 mg (2.0 mL) plus ritonavir 32 mg (0.4 mL†) 11 to < 12 kg* — darunavir 220 mg (2.2 mL) plus ritonavir 32 mg (0.4 mL†) 12 to < 13 kg* — darunavir 240 mg (2.4 mL) plus ritonavir 40 mg (0.5 mL†) 13 to < 14 kg* — darunavir 260 mg (2.6 mL) plus ritonavir 40 mg (0.5 mL†) 14 to < 15 kg* — darunavir 280 mg (2.8 mL) plus ritonavir 48 mg (0.6 mL†) 15 to < 30 kg — darunavir 375 mg (combination of tablets or 3.8 mL‡) plus ritonavir 48 mg (0.6 mL†) 30 to < 40 kg — darunavir 450 mg (combination of tablets or 4.6 mL‡) plus ritonavir 100 mg (tablet or 1.25 mL†) ≥40 kg — darunavir 600 mg (tablet or 6 mL) plus ritonavir 100 mg (tablet or 1.25 mL†) * The dose in children weighing 10–15 kg is 20 mg/kg darunavir and 3 mg/kg ritonavir per kg body weight per dose, which is higher than the weight-adjusted dose in children with higher weight. † Ritonavir 80 g/mL oral solution ‡ The 375-mg and 450-mg darunavir doses are rounded for suspension-dose convenience.

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Lopinavir (LPV)/ritonavir (RTV) (Kaletra, AbbVie Inc., North Chicago, Illinois)	200/50-mg tablets 100/25-mg tablets 80/20-mg/mL oral solution	**Side effects:** Nausea, vomiting, diarrhea **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Do not administer to neonates before a postmenstrual age (first day of the mother's last menstrual period to birth plus the time elapsed after birth) of ≥42 weeks and a postnatal age of ≥14 days. **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life-threatening adverse events.	**Children aged 14 days–12 months, per body weight** Suspension (lopinavir/ritonavir) • 16/4 mg/kg or 300/75 mg/m^2 twice daily **Children aged > 12 months–18 years, per body weight** Suspension (lopinavir/ritonavir) • < 15 kg, 12/3 mg/kg twice daily • ≥ 15 kg to 40 kg, 10/2.5 mg/kg twice daily • > 40 kg, 400/100 mg twice daily • not to exceed the recommended adult dose (400/100 mg [5 mL] twice daily **Children aged > 12 months–18 years** Tablet, weight-based dosing (lopinavir/ritonavir) • 15 to 25 kg, 2 100/25-mg tablets twice daily • > 25 to 35 kg, 3 100/25-mg tablets twice daily • > 35 kg, 4 100/25-mg tablets twice daily or 2 200/50-mg tablets twice daily
Ritonavir[b] (RTV) (Norvir, AbbVie, Inc., North Chicago, Illinois)	100-mg tablets 100-mg soft gelatin capsules 80-mg/mL oral solution	**Side effects:** Abdominal pain, asthenia, headache, malaise, anorexia, diarrhea, dyspepsia, nausea, vomiting, circumoral paresthesia, peripheral paresthesia, dizziness, and taste perversion. **Cautions:** PR and QT interval prolongation have been reported. Use with caution with patients at risk for cardiac conduction abnormalities or receiving other drugs with similar effect. Can cause hepatotoxicity, pancreatitis, or hyperglycemia **Contraindications:** Co-administration of ritonavir with certain sedative hypnotics, antiarrhythmics, sildenafil, or ergot alkaloid preparations is contraindicated and might result in potentially life-threatening adverse events.	• See pediatric dosage for use as a boosting agent with darunavir or lopinavir in respective darunavir and lopinavir sections of this table.

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Zidovudine (ZDV; AZT) (Retrovir, ViiV Healthcare, Brentford, Middlesex, United Kingdom)	100-mg capsule 300-mg tablet 10-mg/mL oral syrup 10-mg/mL intravenous infusion	**Side effects:** Nausea, vomiting, headache, insomnia, and fatigue **Cautions:** Can cause anemia and neutropenia	**Infants aged birth–41 days** **Full term (aged ≥35 weeks gestation at birth), per body weight** Syrup • 4 mg/kg orally twice daily Intravenous[c] • 3.0 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged ≥30 to 35 weeks gestation at birth; from birth through day 14 of life; switch to full term infant dose at 15 days of life), per body weight** Syrup • 2 mg/kg orally twice daily Intravenous[c] • 1.5 mg/kg, infused over 30 minutes, every 12 hours **Premature (aged <30 weeks gestation at birth; day 14–28 of life; switch to full term infant dose at 29 days* of life), per body weight** Syrup • 2 mg/kg orally twice daily Intravenous[c] • 1.5 mg/kg, infused over 30 minutes, every 12 hours **Infants and children aged ≥35 weeks post-conception and at least 4 weeks post-delivery, per body weight** Syrup or Capsules • 4 to <9 kg, 12 mg/kg twice daily • 9 to <30 kg, 9 mg/kg twice daily Tablet • ≥30 kg, 300-mg tablet twice daily * Note: Premature infants exposed to HIV after day 1 of life are switched to full-term infant dose at 29 days of life.

3227

Drug	Formulation	Side effects, contraindications, and cautions	Dose adjustments
Lamivudine (3TC) (Epivir, ViiV Healthcare, Brentford Middlesex, United Kingdom)	150-mg scored tablet 100-mg tablet 300-mg tablet 10-mg/mL oral solution	**Side effects:** Headache, nausea, malaise and fatigue, nasal signs and symptoms, diarrhea, and cough **Cautions:** 3TC may be used in nPEP regimens for patients with chronic hepatitis B infection, but hepatic function tests should be closely monitored when regimen is stopped since withdrawal of this drug may cause an acute hepatitis exacerbation. **Contraindications:** Do not administer with emtricitabine	**Neonates and infants, aged ≤27 days** Oral solution • 2 mg/kg twice daily **Children, aged ≥4 weeks** Oral solution • 4 mg/kg (maximum dose 150 mg) twice daily **Children aged <16 years and weighing ≥14 kg** Scored 150-mg tablet • 14 to <20 kg, 75 mg (1/2 tablet) AM + 75 mg (1/2 tablet) PM • 20 to <25 kg, 75 mg (1/2 tablet) AM + 150 mg (1 tablet) PM • ≥25 kg, 150 mg tablet twice daily **Adolescents (aged ≥16 years) and adults, per body weight** • <50 kg, 4 mg/kg (up to 150 mg) twice daily • ≥50 kg, 150 mg twice daily or 300 mg once daily

Abbreviations: eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females); nPEP, nonoccupational postexposure prophylaxis.

[a] For most current dosing regimens for treatment naïve children, see 1) AIDSInfo Drugs Database at http://aidsinfo.nih.gov/drugs, 2) Drugs@FDA (FDA approved drug products index) at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/, 3) Pediatric ARV treatment guidelines at http://aidsinfo.nih.gov/guidelines/html/2/pediatric-treatment-guidelines/0#, and 4) Perinatal guidelines at http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0

[b] Ritonavir is used in clinical practice as a pharmacokinetic enhancer to increase the trough concentration and prolong the half-life of darunavir, lopinavir, and other protease inhibitors

[c] Infants unable to receive oral dosing may receive intravenous dosing

Health care providers might consider using antiretroviral regimens for nPEP other than those listed as preferred or alternative because of patient-specific information (e.g., an HIV-infected exposure source with known drug-resistance or contraindications to ≥1 of the antiretrovirals in a preferred regimen). In those cases, health care providers are encouraged to seek consultation with other health care providers knowledgeable in using antiretroviral medications for similar patients (e.g., children, pregnant women, those with comorbid conditions) (Appendix 4).

> Providers should be aware that abacavir sulfate (Ziagen, ViiV Healthcare, Brentford, Middlesex, United Kingdom) should not be prescribed in any nPEP regimen. Prompt initiation of nPEP does not allow time for determining if a patient has the *HLA-B*5701* allele, the presence of which is strongly associated with a hypersensitivity syndrome that can be fatal.[183]

Health care providers and patients who are concerned about potential adherence and toxicity or the additional cost associated with a 3-drug antiretroviral regimen might consider using a 2-drug regimen (i.e., a combination of 2 NRTIs or a combination of a PI and a NNRTI). However, this DHHS guideline recommends a 3-drug regimen in all cases when nPEP is indicated.

VII-D. Prophylaxis for STIs and Hepatitis

All adults and adolescents with exposures by sexual assault should be provided with prophylaxis routinely for STIs and HBV,[174] as follows:

- For gonorrhea, (male and female adults and adolescents),
  - ceftriaxone 250 mg intermuscular, single dose;
  - ***plus*** azithromycin, 1 g, orally, single dose;
- For chlamydia (male and female adults and adolescents),
  - azithromycin, 1 g, orally, single dose
  - ***or*** doxycycline, 100 mg, orally, twice a day for 7 days.
- For trichomonas (female adults and adolescents),
  - metronidazole, 2 g, orally, single dose
  - ***or*** tinidazole, 2 g, orally, single dose

All persons not known to be previously vaccinated against HBV, should receive hepatitis B vaccination (without hepatitis B immune globulin),[174] with the first dose administered during the initial examination. If the exposure source is available for testing and is HBsAg-positive, unvaccinated nPEP patients should receive both hepatitis B vaccine and hepatitis B immune globulin during the initial evaluation. Follow-up vaccine doses should be administered during 1–2 months and at 4–6 months after the first nPEP dose. Previously vaccinated sexually assaulted persons who did not receive postvaccination testing should receive a single vaccine booster dose.

HPV vaccination is recommended for female survivors aged 9–26 years and male survivors aged 9–21 years. For MSM with who have not received HPV vaccine or who have been incompletely vaccinated, vaccine can be

administered through age 26 years. The vaccine should be administered to sexual assault survivors at the time of the initial examination, and follow-up dose administered at 1–2 months and 6 months after the first dose.[174]

Routine use of STI prophylaxis is not recommended for sexually abused or assaulted children.[174]

VII-E. Considerations for All Patients Treated with Antiretroviral nPEP

The patient prescribed nPEP should be counseled regarding potential associated side effects and adverse events specific to the regimen prescribed. Any side effects or adverse events requiring immediate medical attention should be emphasized.

VII-E1. Provision of nPEP Starter Packs or a 28-day Supply at Initiation

Patients might be under considerable emotional stress when seeking care after a potential HIV exposure and might not be attentive to, or remember, all the information presented to them before making a decision regarding nPEP. Health care providers should consider giving an initial prescription for 3–7 days of medication (i.e., a starter pack) or an entire 28-day course and scheduling an early follow-up visit. Provision of the entire 28-day nPEP medication supply at the initial visit rather than a starter pack of 3–7 days has been reported to increase likelihood of adherence, especially when patients find returning for multiple follow-up visits difficult.[96,184] Routinely providing starter packs or the entire 28-day course requires that health care providers stock nPEP drugs in their practice setting or have an established agreement with a pharmacy to stock, package and urgently dispense nPEP drugs with required administration instructions. At the patient's second visit, health care providers can discuss the results of baseline HIV blood testing (if rapid tests were not used), provide additional counseling and support, assess medication side effects and adherence, or provide an altered nPEP medication regimen if indicated by side effects or laboratory test results. nPEP starter packs or 28-day supplies might also include such medications as antiemetics to alleviate recognized side effects of the specific medications prescribed, if they occur. Health care providers should counsel patients regarding which side effects might occur (Table 6), how to manage them, and when to contact the provider if they do not resolve.[173]

VII-E2. Expert Consultation

When health care providers are inexperienced with prescribing or managing patients on antiretroviral medications or when information from persons who were the exposure source indicates the possibility of antiretroviral resistance, consultation with infectious disease or other HIV-care specialists, if available immediately, is warranted before prescribing nPEP to determine the correct regimen. Similarly, consulting with specialists with experience using antiretroviral drugs is advisable when considering prescribing nPEP for certain persons—pregnant women (infectious disease specialist or obstetrician), children (pediatrician), or persons with renal dysfunction (infectious disease specialist or nephrologist). However, if such consultation is not available immediately, nPEP should be initiated promptly and, if necessary, revised after consultation is obtained. Expert consultation can be obtained by calling the PEPline at the National Clinician's Consultation Center at 888-448-4911 (additional information is available at http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/).

VII-E3. Facilitating Adherence

Observational studies have reported that adherence to nPEP regimens is often inadequate and has been especially so among sexual assault survivors. Medication adherence can be facilitated by (1) prescribing medications with fewer side effects, fewer doses per day, and fewer pills per dose; (2) educating the patient

regarding potential side effects of the specific medications prescribed and providing medications to assist if side effects occur (e.g., antiemetics); (3) recommending medication adherence aids (e.g., pill boxes); (4) helping patients incorporate doses into their daily schedules; and (5) providing a flexible and proactive means for patient–health care provider contact during the nPEP period.[185,186] Also, establishing a trusting relationship and maintaining good communication about adherence can help to improve completion of the nPEP course. Adherence to the nPEP medications prescribed to children will depend on the involvement of and support provided to parents and guardians.

VII-E4. HIV Prevention Counseling

The majority of persons who seek care after a possible HIV exposure do so because of failure to initiate or maintain effective risk-reduction behaviors. Notable exceptions are sexual assault survivors and persons with community-acquired needlestick injuries.

Although nPEP can reduce the risk for HIV infection, it is not always effective. Therefore, patients should practice protective behaviors with sex partners (e.g., consistent condom use) or drug-use partners (e.g., avoidance of shared injection equipment) throughout the nPEP course to avoid transmission to others if they become infected and after nPEP to avoid future HIV exposures.

At follow-up visits, when indicated, health care providers should assess their patients' needs for behavioral intervention, education, and services. This assessment should include frank, nonjudgmental questions about sexual behaviors, alcohol use, and illicit drug use. Health care providers should help patients identify ongoing risk concerns and develop plans for improving their use of protective behaviors.[187]

To help patients obtain indicated interventions and services, health care providers should be aware of local resources for high-quality HIV education and ongoing behavioral risk reduction, counseling and support, inpatient and outpatient alcohol and drug-treatment services, family and mental health counseling services, and support programs for HIV-infected persons. Information regarding publicly funded HIV prevention programs can be obtained from state or local health departments.

VII-E5. Providing PrEP After nPEP Course Completion

Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of nPEP should be offered PrEP[11] at the conclusion of their 28-day nPEP medication course. Because no evidence exists that prophylactic antiretroviral use delays seroconversion and nPEP is highly effective when taken as prescribed, a gap is unnecessary between ending nPEP and beginning PrEP. Upon documenting HIV-negative status, preferably by using an Ag/Ab test, daily use of the fixed dose combination of TDF (300mg) and FTC (200 mg) can begin immediately for patients for whom PrEP is indicated. Clinicians with questions about prescribing PrEP, are encouraged to call the PrEPline 855-448-7737 at the National Clinician Consultation Center or go to their website (http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/).

VII.E6. Providing nPEP in the Context of PrEP

Patients fully adhering to a daily PrEP regimen as recommended by their health care practitioner are not in need of nPEP if they experience a potential HIV exposure while on PrEP. PrEP is highly effective when taken daily or near daily.[11,188] For patients who report that they take their PrEP medication sporadically and those who did not take it within the week before the recent exposure, initiating a 28-day course of nPEP might be indicated. In

that instance, all nPEP baseline and follow-up laboratory evaluations should be conducted. After the 28-day nPEP regimen is completed, if confirmed to be HIV uninfected, the daily PrEP regimen can be reinitiated.

VII-E7. Management of Source Persons with HIV Infection

When persons who were the exposure source are present during the course of evaluating a patient for potential HIV exposure, health care providers should also assess that person's access to relevant medical care, behavioral intervention, and social support services. If needed care cannot be provided directly, health care providers should help HIV-infected source persons obtain care in the community (http://locator.aids.gov/).

VII-F. Additional Considerations

VII-F1. Reporting and Confidentiality

As with all clinical care, health care providers should handle nPEP evaluations with confidentiality. Confidential reporting of STIs and newly diagnosed HIV infections to health departments should occur as indicated by that jurisdiction's local laws and regulations.

For cases of sexual assault, health care providers should document their findings and assist patients with notifying local authorities.[174] How health care providers should document and report their findings is beyond the scope of these guidelines. Laws in all 50 states strictly limit the evidentiary use of a survivor's previous sexual history, including evidence of previously acquired STIs, to avoid efforts to undermine the credibility of the survivor's testimony. Evidentiary privilege against revealing any aspect of the survivor's examination or medical treatment also is enforced in the majority of most states.

Certain states and localities have special programs that provide reimbursement for medical therapy, including antiretroviral medication after sexual assault, and those areas might have specific reporting requirements. In all states, sexually assaulted persons are eligible for reimbursement of medical expenses through the U.S. Department of Justice Victim's Compensation Program in cases where the sexual assault is reported to the police (http://www.ojp.usdoj.gov/ovc/map.html).When the sexual abuse of a child is suspected or documented, the clinician should report it in compliance with that jurisdiction's laws and regulations.

VII-F2. Special Populations

VII-F2a. Sexually Assaulted Persons

Eighteen percent of a national sample of adult women in the United States reported having ever been raped, and approximately 1 in 10 women (9.4%) has been raped by an intimate partner during her lifetime.[189] Sexual assault also occurs among men. Approximately 1 in 71 men (1.4%) in the United States has been raped at some time in his life.[189] In 1 series from an ED, 5% of reported rapes involved men sexually assaulted by men.[190]

Sexual assault typically has multiple characteristics that increase the risk for HIV transmission if the assailant is infected. In 1 prospective study of 1,076 sexually assaulted person, 20% had been attacked by multiple assailants, 39% had been assaulted by strangers, 17% had had anal penetration, and 83% of females had been penetrated vaginally. Genital trauma was documented among 53% of those assaulted, and sperm or semen was detected in 48%.[191] Often, in both stranger and intimate-partner rape, condoms are not used[192,193] and STIs are frequently contracted.[194-197] In the largest study[198] examining prevalence of HIV infection among sexual assailants, 1% of men convicted of sexual assault in Rhode Island were HIV infected when they entered prison, compared with 3% of all prisoners and 0.3% of the general male population.

Persons provided nPEP after sexual assault or child sexual abuse should be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Local SANE programs can be located at http://www.sane-sart.com/. Patients who have been sexually assaulted will benefit from supportive services to improve adherence to nPEP if it is prescribed, and from crisis, advocacy, and counseling services provided by sexual assault crisis centers.

VII-F2b. Pregnant Women and Women with Childbearing Potential

Information is being collected regarding safe use of antiretroviral drugs for pregnant and breastfeeding women who do not have HIV infection, particularly those whose male partners have HIV infection and who use antiretrovirals as PrEP.[114] Because considerable experience has been gained in recent years in the safe and recommended use of antiretroviral medications during pregnancy and breastfeeding among women with HIV infection—either for the benefit of the HIV-infected woman's health or to prevent transmission to newborns—and because of the lack of similar experience in HIV-uninfected pregnant women, nPEP drug recommendations (Table 5) rely on those used for HIV-infected women during pregnancy and breastfeeding.

Health care providers should be aware that certain medications are contraindicated for use as nPEP among potentially or actually pregnant women as follows (Table 7):

- Efavirenz (EFV) is classified as FDA pregnancy Category D because of its potential teratogenicity when used during the first 5–6 weeks of pregnancy.[199] It should be avoided in nPEP regimens for HIV-uninfected women during the first trimester and should not be used for women of childbearing age who might become pregnant during an antiretroviral prophylaxis course. For all women with childbearing potential, pregnancy testing must be done before the EFV initiation, and women should be counseled regarding potential risks to the fetus and the importance of avoiding pregnancy while on an EFV-containing regimen.[114]
- Prolonged use of stavudine (d4T) in combination with didanosine (DDI) for HIV-infected pregnant women has been associated with maternal and fetal morbidity attributed to lactic acidosis; therefore, this combination is not recommended for use in an nPEP regimen during pregnancy.[123,124]
- Because using indinavir (IDV) is associated with increased risk for nephrolithiasis among pregnant women and its use without co-administration of a ritonavir as a boosting agent can result in substantially decreased plasma levels of IDV (the active agent) among pregnant women, IDV should not be used as nPEP for pregnant women.
- Severe hepatotoxicity has been observed among patients administered nevirapine (NVP)-containing nPEP regimens (regardless of pregnancy status); therefore, NVP is contraindicated for nPEP, including for pregnant women.[83]

Table 7. Antiretroviral medications that should not be used for nPEP among pregnant women

Antiretroviral	Risk in pregnancy	Concern
Efavirenz	Teratogenicity	Fetal safety
Nevirapine	Hepatotoxicity	Maternal safety
Stavudine and didanosine	Mitochondrial toxicity and lactic acidosis	Maternal safety
Indinavir (without co-administration with ritonavir) during second or third trimester	Substantially decreased plasma concentration; risk for nephrolithiasis	Efficacy and maternal safety
Abbreviation: nPEP, nonoccupational postexposure prophylaxis.		

If nPEP is prescribed to a woman who is pregnant at the time of exposure or becomes pregnant while on nPEP, health care providers should enter the patient's information (anonymously) into the Antiretroviral Pregnancy Registry (http://www.apregistry.com).

VII-F2c. Incarcerated Persons

Approximately 2 million persons are incarcerated in jails and prisons and can be at risk for HIV infection acquisition during incarceration. Studies have indicated that the risk for becoming infected while incarcerated is probably less than the risk outside a facility[200-202]; nevertheless, correctional facilities should develop protocols for nPEP to help reduce the legal, emotional and medical problems associated with an exposure event for this vulnerable population. As foundation for nPEP provision when it is indicated, correctional facilities should provide HIV education, voluntary HIV testing, systems to assist in identifying potential HIV exposures without repercussion for inmates, and provision of nPEP evaluation and medication. Sexual assaults in particular can put inmates at risk for HIV acquisition and inmates may engage in behaviors that put them at risk for HIV acquisition both prior to being incarcerated and upon reentry into the community. A 15-minute interactive educational program designed to educate inmates about nPEP resulted in a 40% increase in knowledge compared to baseline regardless of inmate-related demographics or HIV-risk characteristics.[203]

The federal Bureau of Prisons has published a clinical practice guideline that integrates guidance for nonoccupational and occupational HIV-related exposures.[204] Those guidelines specific to nPEP represent an adaptation of the 2005 CDC nPEP guidelines and outline HIV postexposure management recommendations for the different exposure types. The federal Bureau of Prisons nPEP recommendations can be modified for use in correctional facilities of varying sizes and resources. The Bureau of Prisons guidelines provide practical materials for both correctional health care providers and inmates and include worksheets to assist health care providers in systematically documenting HIV exposures and nPEP therapy management, and sample patient consent forms. They recommend that each correctional facility develop its own postexposure management protocol. The CDC recommends that health care providers should make every effort to use of current CDC guidelines related to selection of nPEP antiretrovirals.

VII-F2d. PWID

A history of injection drug use should not deter health care providers from prescribing nPEP if the exposure provides an opportunity to reduce the immediate risk for acquisition of HIV infection. A survey of health care providers who treat PWID determined a high degree of willingness to provide nPEP after different types of potential HIV exposure.[202]

When evaluating whether exposures are isolated, episodic, or ongoing, health care providers should assess whether persons who continue to engage in injecting or sexual HIV risk behaviors are practicing risk reduction (e.g., not sharing syringes, using a new sterile syringe for each injection, and using condoms with every partner or client). For certain persons, a high-risk exposure might be an exceptional occurrence and merit nPEP despite their ongoing general risk behavior. For other persons, the risk exposures might be frequent enough to merit consideration of PrEP either instead of nPEP or after a 28-day nPEP course.

PWID should be assessed for their interest in substance abuse treatment and their knowledge and use of safe injecting and sexual practices. Patients desiring substance abuse treatment should be referred for such treatment. Persons who continue to inject or who are at risk for relapse to injection drug use should be instructed regarding use of a new sterile syringe for each injection and the importance of avoiding sharing injection equipment. In areas where programs are available, health care providers should refer such patients to sources of sterile injection equipment. When sexual practices can result in ongoing risk for HIV acquisition, referral for sexual risk-reduction interventions is recommended.

None of the preferred or alternative antiretroviral drugs recommended for nPEP in Table 5 have substantial interactions with methadone or buprenorphine. However, other antiretrovirals might decrease or increase methadone levels; therefore, health care providers electing to use antiretrovirals not specifically recommended for nPEP should check for interactions before prescribing to persons on opiate substitution therapy. For example, RTV-boosted DRV can decrease methadone levels marginally (within acceptable clinical range), and careful monitoring for signs and symptoms of withdrawal is advised.[205]

VII-F3. Special Legal and Regulatory Concerns

VII-F3a. HIV Testing of Exposure Source Patients

When approaching persons who were the exposure source for patients being considered for nPEP, health care providers should be aware of potential legal concerns related to requesting them to undergo HIV testing. During 2011, a total of 33 states had ≥ 1 HIV-specific criminal exposure laws.[206] These laws focus explicitly on persons living with HIV. HIV-specific criminal laws criminalize or impose additional penalties on certain behaviors (e.g., sexual activity or needle-sharing without disclosure of HIV-positive status) and sex offenses. In jurisdictions where consent to HIV testing might invoke legal repercussions (see http://www.cdc.gov/hiv/policies/law/states/), the exposure source person should be made aware of possible legal jeopardies. Health care providers can opt instead to make nPEP treatment decisions without HIV testing of the source.

VII-F3b. Adolescents and Clinical Preventive Care

Health care providers should be aware of local laws and regulations that govern which clinical services adolescent minors can access with or without prior parental consent. In certain jurisdictions, minors of particular ages can access contraceptive services, STI diagnosis and treatment, or HIV testing without parental or guardian consent. In fewer settings, minors can access clinical preventive care (e.g. vaccines, nPEP, or PrEP).[207] To provide and coordinate care when a minor presents for possible nPEP, health care providers should understand their local regulations and institutional policies guiding provision of clinical preventive care to adolescent minors.

VII-F4. Potential Sources of Financial Assistance for nPEP Medication

Antiretroviral medications are expensive, and certain patients are unable to cover the out-of-pocket costs. When public, privately purchased, or employer-based insurance coverage is unavailable, health care providers can assist patients with obtaining antiretroviral medications through the medication assistance programs of the pharmaceutical companies that manufacture the prescribed medications. Applications are available online that can be faxed to the company or certain companies can be called on an established phone line. Requests for assistance often can be handled urgently so that accessing medication is not delayed. Information for specific medications and manufacturers is available at http://www.pparx.org/en/prescription_assistance_programs/list_of_participating_programs.

Additionally, persons being prescribed nPEP after sexual assault can be reimbursed for medications and clinical care costs through state Crime Victim's Compensation Programs funded by the U.S. Department of Justice. Contact information for each state is available at http://www.ojp.usdoj.gov/ovc/map.html or http://www.nacvcb.org/index.asp?bid=16.

VIII. Conclusion

Accumulated data from human clinical and observational studies, supported by data from animal studies, indicate that using antiretroviral medication initiated as soon as possible ≤72 hours after sexual, injection drug use, or other substantial nonoccupational HIV exposure and continued for 28 days might reduce the likelihood of HIV acquisition. Because of these findings, DHHS recommends prompt initiation of nPEP with a combination of antiretroviral medications when persons seek care ≤72 hours after exposure, the source is known to be HIV infected, and the exposure event presents a substantial risk for HIV acquisition by an exposed, uninfected person. When the HIV status of the source is unknown and the patient seeks care ≤72 hours after exposure, DHHS does not recommend for or against nPEP, but encourages health care providers and patients to weigh the risks and benefits on a case-by-case basis. When the HIV acquisition risk is negligible or when patients seek care > 72 hours after a substantial exposure, nPEP is not recommended. A 3-drug nPEP regimen is recommended for all persons for whom nPEP is indicated. Providing a 28-day nPEP supply or a 3–7 day nPEP starter pack at initiation of nPEP might improve adherence. Providing medications to ameliorate specific side effects for the antiretrovirals prescribed might improve adherence to the nPEP regimen. Figure 2 includes a summary of key nPEP considerations.

Figure 2. nPEP considerations summary

Initial nPEP Evaluation

- Obtain history of potential exposure event
  - HIV and HBV status of exposed person and source person, if available
  - Timing of most recent potential exposure
  - Type of exposure event and risk for HIV acquisition
  - Make determination if nPEP is indicated
- If nPEP is indicated
  - Conduct laboratory testing
    - HIV blood test (rapid combined Ag/Ab test, if available)
    - STIs, HBV, HCV, pregnancy, and chemistries, as indicated
  - Prescribe 28-day nPEP course
    - Educate patient about potential regimen-specific side effects and adverse events
    - Counsel patient about medication adherence
    - Provide patient with nPEP prescription or full 28-day nPEP course or nPEP starter pack and prescription
  - When necessary, assist patients with obtaining nPEP medication through a medication assistance program for the prescribed regimen
- For all persons evaluated
  - Prescribe prophylaxis for STIs and HBV infection, if indicated
  - Provide counseling related to HIV prevention strategies, as appropriate
  - Document sexual assault findings and fulfill local reporting requirements
  - Conduct confidential reporting of newly diagnosed STIs and HIV infection to health department
  - Link HIV-infected persons to relevant medical and psychosocial support services

Follow-up evaluations for persons prescribed nPEP

- Conduct HIV and any other indicated laboratory testing
- Consider changing nPEP regimen if indicated by side effects or results of initial testing
- Provide additional counseling and support for medication adherence and HIV prevention, if indicated

Abbreviations: Ag/Ab, antigen/antibody combination test; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; STI, sexually transmitted infection.

VIII-A. Plans for Updating These Guidelines

These guidelines are intended to assist U.S. health care providers in reducing the occurrence of new HIV infections through the effective delivery of nPEP to the patients most likely to benefit. As new medications and new information regarding nPEP become available, these guidelines will be revised and published.

IX. REFERENCES

1. Smith DK, Grohskopf LA, Black RJ, et al. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. *MMWR Recomm Rep.* 2005;54(No. RR-2):1-20.
2. Kuhar DT, Henderson DK, Struble KA, et al. Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol.* 2013;34(9):875-892.
3. New York State Department of Health AIDS Institute. HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault New York, NY: New York State Department of Health AIDS Institute; 2014: available at http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis/hiv-prophylaxis-following-non-occupational-exposure/. Accessed October 2, 2015.
4. Nonoccupational HIV PEP Task Force, Brown University AIDS Program, Rhode Island Department of Health. Nonoccupational human immunodeficiency virus postexposure prophylaxis guidelines for Rhode Island healthcare practitioners. Providence, Rhode Island,2002: available at http://www.health.state.ri.us/publications/guidelines/provider/NonoccupationalHIVPostexposureProphalaxis.pdf.
5. The California Task Force on Non-Occupational PEP, the California Department of Health Services, Office of AIDS. Offering HIV Post-Exposure Prophylaxis (PEP) Following Non-Occupational Exposures Recommendations for Health Care Providers in the State of California Sacramento, California,2004: available at http://www.cdph.ca.gov/programs/aids/Documents/RPT2004OfferingPEPFollowingNonOccupExp2004-06.pdf.
6. Havens PL, American Academy of Pediatrics Committee on Pediatric AIDS. Postexposure prophylaxis in children and adolescents for nonoccupational exposure to human immunodeficiency virus. *Pediatrics.* 2003;111(6):1475-1489.
7. Marrazzo JM, del Rio C, Holtgrave DR, et al. HIV prevention in clinical care settings: 2014 recommendations of the International Antiviral Society-USA Panel. *JAMA.* 2014;312(4):390-409.
8. Ford N, Mayer KH, World Health Organization Postexposure Prophylaxis Guideline Development Group. World Health Organization Guidelines on Postexposure Prophylaxis for HIV: Recommendations for a Public Health Approach. *Clin Infect Dis.* 2015;60 Suppl 3:S161-164.
9. Tolle MA, Schwarzwald HL. Postexposure prophylaxis against human immunodeficiency virus. *Am Fam Physician.* 2010;82(2):161-166.
10. American College of Emergency Physicians. Emergency Management of the Sexually Assaulted or Sexually Abused Patient In: Riviello RJ, Rozzi H, eds. 2nd Edition ed. Irving, Texas: American College of Emergency Physicians; 2013: http://www.acep.org/workarea/DownloadAsset.aspx?id=93246. Accessed 12/10/2015.
11. Centers for Disease Control and Prevention (CDC), US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2014-A Clinical Practice Guideline. Atlanta, GA: US Department of Health and Human Services, CDC; 2014: available at http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf. Accessed October 5, 2015.
12. Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *New Engl J Med.* 1997;337(21):1485-1490.
13. Terzi R, Niero F, Iemoli E, Capetti A, Coen M, Rizzardini G. Late HIV seroconversion after non-occupational postexposure prophylaxis against HIV with concomitant hepatitis C virus seroconversion. *AIDS.* 2007;21(2):262-263.
14. Donnell D, Mimiaga MJ, Mayer K, Chesney M, Koblin B, Coates T. Use of non-occupational post-exposure prophylaxis does not lead to an increase in high risk sex behaviors in men who have sex with men participating in the EXPLORE trial. *AIDS Behav.* 2010;14(5):1182-1189.

15. Sonder GJB, Prins JM, Regez RM, et al. Comparison of two HIV postexposure prophylaxis regimens among men who have sex with men in Amsterdam: adverse effects do not influence compliance. *Sex Transm Dis.* 2010;37(11):681-686.

16. Schechter M, do Lago RF, Mendelsohn AB, et al. Behavioral impact, acceptability, and HIV incidence among homosexual men with access to postexposure chemoprophylaxis for HIV. *J Acquir Immune Defic Syndr.* 2004;35(5):519-525.

17. McAllister J, Read P, McNulty A, Tong WW, Ingersoll A, Carr A. Raltegravir-emtricitabine-tenofovir as HIV nonoccupational post-exposure prophylaxis in men who have sex with men: safety, tolerability and adherence. *HIV Med.* 2014;15(1):13-22.

18. Jain S, Oldenburg CE, Mimiaga MJ, Mayer KH. Subsequent HIV infection among men who have sex with men who used non-occupational post-exposure prophylaxis at a Boston community health center: 1997-2013. *AIDS Patient Care STDS.* 2015;29(1):20-25.

19. Foster R, McAllister J, Read TR, et al. Single-tablet emtricitabine-rilpivirine-tenofovir as HIV postexposure prophylaxis in men who have sex with men. *Clin Infect Dis.* 2015:1-5.

20. Chacko L, Ford N, Sbaiti M, Siddiqui R. Adherence to HIV post-exposure prophylaxis in victims of sexual assault: a systematic review and meta-analysis. *Sex Transm Infect.* 2012;88(5):335-341.

21. Draughon JE, Sheridan DJ. Nonoccupational postexposure prophylaxis for human immunodeficiency virus in Sub-Saharan Africa: a systematic review. *J Forensic Nurs.* 2011;7(2):89-96.

22. Draughon JE, Sheridan DJ. Nonoccupational postexposure prophylaxis following sexual assault in industrialized low-HIV-prevalence countries: a review. *Psychol Health Med.* 2012;17(2):235-254.

23. Loutfy MR, Macdonald S, Myhr T, et al. Prospective cohort study of HIV post-exposure prophylaxis for sexual assault survivors. *Antivir Ther.* 2008;13(1):87-95.

24. Lurie P, Miller S, Hecht F, Chesney M, Lo B. Postexposure prophylaxis after nonoccupational HIV exposure: clinical, ethical, and policy considerations. *JAMA.* 1998;280(20):1769-1773.

25. Claydon E, Murphy S, Osborne EM, Kitchen V, Smith JR, Harris JR. Rape and HIV. *Int J STD AIDS.* 1991;2(3):200-201.

26. Myles JE, Hirozawa A, Katz MH, Kimmerling R, Bamberger JD. Postexposure prophylaxis for HIV after sexual assault. *JAMA.* 2000;284(12):1516-1518.

27. Fong C. Post-exposure prophylaxis for HIV infection after sexual assault: when is it indicated? *Emerg Med J.* 2001;18(4):242-245.

28. Albert J, Wahlberg J, Leitner T, Escanilla D, Uhlen M. Analysis of a rape case by direct sequencing of the human immunodeficiencey virus type-1 *pol* and *gag* genes. *J Virol.* 1994;68(9):5918-5924.

29. Murphy S, Kitchen V, Harris JRW, Forster SM. Rape and subsequent seroconversion to HIV. *BMJ.* 1989;299(6701):718-718.

30. Linden JA, Oldeg P, Mehta SD, McCabe KK, LaBelle C. HIV postexposure prophylaxis in sexual assault: current practice and patient adherence to treatment recommendations in a large urban teaching hospital. *Acad Emerg Med.* 2005;12(7):640-646.

31. Griffith WF, Ackerman GE, Zoellner CL, Sheffield JS. Sexual assault: a report on human immunodeficiency virus postexposure prophylaxis. *Obstet Gynecol Int.* 2010;2010(196963):1-6.

32. Olshen E, Hsu K, Woods ER, Harper M, Harnisch B, Samples CL. Use of human immunodeficiency virus postexposure prophylaxis in adolescent sexual assault victims. *Arch of Pediat Adolesc Med.* 2006;160(7):674-680.

33. Carrieri MP, Bendiane MK, Moatti JP, Rey D. Access to HIV prophylaxis for survivors of sexual assault: the tip of the iceberg. *Antivir Ther.* 2006;11(3):391-392.

34. Krause KH, Lewis-O'Connor A, Berger A, et al. Current practice of HIV postexposure prophylaxis treatment for sexual assault patients in an emergency department. *Women Health Iss.* 2014;24(4):e407-412.

35. Girardet RG, Lemme S, Biason TA, Bolton K, Lahoti S. HIV post-exposure prophylaxis in children and adolescents presenting for reported sexual assault. *Child Abuse Negl.* 2009;33(3):173-178.

36. Schremmer RD, Swanson D, Kraly K. Human immunodeficiency virus postexposure prophylaxis in child and adolescent victims of sexual assault. *Pediatr Emerg Care.* 2005;21(8):502-506.

37. Ellis JC, Ahmad S, Molyneux EM. Introduction of HIV post-exposure prophylaxis for sexually abused children in Malawi. *Arch Dis Child.* 2006;90(12):1297-1299.

38. Neu N, Heffernan-Vacca S, Millery M, Stimell M, Brown J. Postexposure prophylaxis for HIV in children and adolescents after sexual assault: a prospective observational study in an urban medical center. *Sex Transm Dis.* 2007;34(2):65-68.

39. Merchant RC, Keshavarz R, Low C. HIV post-exposure prophylaxis provided at an urban paediatric emergency department to female adolescents after sexual assault. *Emerg Med J.* 2004;21(4):449-451.

40. Speight CG, Klufio A, Kilonzo SN, et al. Piloting post-exposure prophylaxis in Kenya raises specific concerns for the management of childhood rape. *Trans R Soc Trop Med Hyg.* 2006;100(1):14-18.

41. Fajman N, Wright R. Use of antiretroviral HIV post-exposure prophylaxis in sexually abused children and adolescents treated in an inner-city pediatric emergency department. *Child Abuse Negl.* 2006;30(8):919-927.

42. Collings SJ, Bugwandeen SR, Wiles WA. HIV post-exposure prophylaxis for child rape survivors in KwaZulu-Natal, South Africa: who qualifies and who complies? *Child Abuse Negl.* 2008;32(4):477-483.

43. Chesshyre ELD, Molyneux EM. Presentation of child sexual abuse cases to Queen Elizabeth Central Hospital following the establishment of an HIV post-exposure prophylaxis programme. *Malawi Med J.* 2009;21(2):54-58.

44. Du Mont J, Myhr TL, Husson H, Macdonald S, Rachlis A, Loutfy MR. HIV postexposure prophylaxis use among Ontario female adolescent sexual assault victims: a prospective analysis. *Sex Transm Dis.* 2008;35(12):973-978.

45. Pierce AB, Yohannes K, Guy R, et al. HIV seroconversions among male non-occupational post-exposure prophylaxis service users: a data linkage study. *Sex Health.* 2011;8(2):179-183.

46. Rey D, Bendiane MK, Bouhnik A-D, Almeda J, Moatti JP, Carrieri MP. Physicians' and patients' adherence to antiretroviral prophylaxis after sexual exposure to HIV: results from South-Eastern France. *AIDS Care.* 2008;20(5):537-541.

47. Siika AM, Nyandiko WM, Mwangi A, et al. The structure and outcomes of a HIV postexposure prophylaxis program in a high HIV prevalence setup in Western Kenya. *J Acquir Immune Defic Syndr.* 2009;51(1):47-53.

48. Tissot F, Erard V, Dang T, Cavassini M. Nonoccupational HIV post-exposure prophylaxis: a 10-year retrospective analysis. *HIV Med.* 2010;11(9):584-592.

49. Tosini W, Muller P, Prazuck T, et al. Tolerability of HIV postexposure prophylaxis with tenofovir/emtricitabine and lopinavir/ritonavir tablet formulation. *AIDS.* 2010;24(15):2375-2380.

50. Wong K, Hughes CA, Plitt S, et al. HIV non-occupational postexposure prophylaxis in a Canadian province: treatment completion and follow-up testing. *Int J STD AIDS.* 2010;21(9):617-621.

51. Olowookere SA, Fatiregun AA. Human immunodeficiency virus postexposure prophylaxis at IBadan, Nigeria. *J Int Assoc Physicians AIDS Care (Chic).* 2010;9(3):187-190.

52. Chan AC, Gough K, Yoong D, Dimeo M, Tan DH. Non-occupational post-exposure prophylaxis for HIV at St Michael's Hospital, Toronto: a retrospective review of patient eligibility and clinical outcomes. *Int J STD AIDS.* 2013;24(5):393-397.

53. Diaz-Brito V, Leon A, Knobel H, et al. Post-exposure prophylaxis for HIV infection: a clinical trial comparing lopinavir/ritonavir versus atazanavir each with zidovudine/lamivudine. *Antivir Ther.* 2012;17(2):337-346.

54. Gulholm T, Jamani S, Poynten IM, Templeton DJ. Non-occupational HIV post-exposure prophylaxis at a Sydney metropolitan sexual health clinic. *Sex Health.* 2013;10(5):438-441.

55. Shoptaw S, Rotheram-Fuller E, Landovitz RJ, et al. Non-occupational post exposure prophylaxis as a biobehavioral HIV-prevention intervention. *AIDS Care* 2008;20(3):376-381.

56. Mayer KH, Mimiaga MJ, Cohen D, et al. Tenofovir DF plus lamivudine or emtricitabine for nonoccupational postexposure prophylaxis (NPEP) in a Boston community health center. *J Acquir Immune Defic Syndr.* 2008;47(4):494-499.

57. Mayer KH, Mimiaga MJ, Gelman M, Grasso C. Raltegravir, tenofovir DF, and emtricitabine for postexposure prophylaxis to prevent the sexual transmission of HIV: safety, tolerability, and adherence. *J Acquir Immune Defic Syndr.* 2012;59(4):354-359.

58. Babl FE, Cooper ER, Damon B, Louie T, Kharasch S, Harris JA. HIV postexposure prophylaxis for children and adolescents. *Am J Emerg Med.* 2000;18(3):282-287.

59. Bogoch II, Scully EP, Zachary KC, et al. Patient attrition between the emergency department and clinic among individuals presenting for HIV nonoccupational postexposure prophylaxis. *Clin Infect Dis.* 2014;58(11):1618-1624.

60. Jain S, Oldenburg CE, Mimiaga MJ, Mayer KH. Longitudinal trends in HIV nonoccupational postexposure prophylaxis use at a Boston community health center between 1997 and 2013. *J Acquir Immune Defic Syndr.* 2015;68(1):97-101.

61. Beymer MR, Bolan RK, Flynn RP, et al. Uptake and repeat use of postexposure prophylaxis in a community-based clinic in Los Angeles, California. *AIDS Res Hum Retrov.* 2014;30(9):848-855.

62. McDougal SJ, Alexander J, Dhanireddy S, Harrington RD, Stekler JD. Non-occupational post-exposure prophylaxis for HIV: 10-year retrospective analysis in Seattle, Washington. *PLoS One.* 2014;9(8):e105030.

63. Fletcher JB, Rusow JA, Le H, Landovitz RJ, Reback CJ. High-risk sexual behavior is associated with post-exposure prophylaxis non-adherence among men who have sex with men enrolled in a combination prevention intervention. *J Sex Transm Dis.* 2013;2013:210403.

64. Thomas HL, Liebeschuetz S, Shingadia D, Addiman S, Mellanby A. Multiple needle-stick injuries with risk of human immunodeficiency virus exposure in a primary school. *Pediatr Infect Dis J.* 2006;25(10):933-936.

65. Papenburg J, Blais D, Moore D, et al. Pediatric injuries from needles discarded in the community: epidemiology and risk of seroconversion. *Pediatrics.* 2008;122(2):e487-e492.

66. de Waal N, Rabie H, Bester R, Cotton MF. Mass needle stick injury in children from the Western Cape. *J of Trop Pediatr.* 2006;52(3):192-196.

67. Russell FM, Nash MC. A prospective study of children with community-acquired needlestick injuries in Melbourne. *J Paediatr Child Health.* 2002;38(3):322-323.

68. Makwana N, Riordan FAI. Prospective study of community needlestick injuries. *Arch Dis Child.* 2005;90(5):523-524.

69. Butsashvili M, Kamkamidze G, Kajaia M, Kandelaki G, Zhorzholadze N. Circumstances surrounding the community needle-stick injuries in Georgia. *J Commun Health.* 2011;36(6):1050-1052.

70. Babl FE, Cooper ER, Kastner B, Kharasch S. Prophylaxis against possible human immunodeficiency virus exposure after nonoccupational needlestick injuries or sexual assaults in children and adolescents. *Arch of Pediatr Adolesc Med.* 2001;155(6):680-682.

71. Al-Hajjar SH, Frayha HH, Al-Hazmi M, et al. Prevention of HIV-1 transmission with postexposure prophylaxis after inadvertent infected blood transfusion. *AIDS.* 2014;28(10):1539-1541.

72. Shaffer N, Chuachoowong R, Mock PA, et al. Short-course zidovudine for perinatal HIV-1 transmission in Bangkok, Thailand: a randomised controlled trial. *Lancet.* 1999;353(9155):773-780.

73. Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVMET 012 randomised trial. *Lancet.* 1999;354(9181):795-802.

74. Moodley D, Moodley J, Coovadia H, et al. A multicenter randomized controlled trial of nevirapine versus a combination of zidovudine and lamivudine to reduce intrapartum and early postpartum mother-to-child transmission of human immunodeficiency virus type 1. *J Infect Dis.* 2003;187(5):725-735.

75. Sperling RS, Shapiro DE, Coombs RW, et al. Maternal viral load, zidovudine treatment, and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *N Engl J Med.* 1996;335(22):1621-1629.

76. Taha TE, Li Q, Hoover DR, et al. Postexposure prophylaxis of breastfeeding HIV-exposed infants with antiretroviral drugs to age 14 weeks: updated efficacy results of the PEPI-Malawi trial. *J Acquir Immune Defic Syndr.* 2011;57(4):319-325.

77. Wade NA, Birkhead GS, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *New Engl J Med.* 1998;339(20):1409-1414.

78. Tsai CC, Follis KE, Sabo A, et al. Prevention of SIV infection in macaques by (R)-9-(2-phosphonylmethoxypropyl)adenine. *Science.* 1995;270(5239):1197-1199.

79. Tsai CC, Emau P, Follis KE, et al. Effectiveness of postinoculation (R)-9-(2-phosphonylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIVmne infection depends critically on timing of initiation and duration of treatment. *J Virol.* 1998;72(5):4265-4273.

80. Le Grand R, Vaslin B, Larghero J, et al. Post-exposure prophylaxis with highly active antiretroviral therapy could not protect macaques from infection with SIV/HIV chimera. *AIDS.* 2000;14(12):1864-1866.

81. Bourry O, Brochard P, Souquiere S, et al. Prevention of vaginal simian immunodeficiency virus transmission in macaques by postexposure prophylaxis with zidovudine, lamivudine and indinavir. *AIDS.* 2009;23(4):447-454.

82. Dobard C, Sharma S, Parikh UM, et al. Postexposure protection of macaques from vaginal SHIV infection by topical integrase inhibitors. *Sci Transl Med.* 2014;6(227):1-9.

83. Otten RA, Smith DK, Adams DR, et al. Efficacy of postexposure prophylaxis after intravaginal exposure of pig-tailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). *J Virol.* 2000;74(20):9771-9775.

84. Irvine C, Egan KJ, Shubber Z, Van Rompay KK, Beanland RL, Ford N. Efficacy of HIV postexposure prophylaxis: systematic review and meta-analysis of nonhuman primate studies. *Clin Infect Dis.* 2015;60 Suppl 3:S165-169.

85. Carries S, Muller F, Muller FJ, Morroni C, Wilson D. Characteristics, treatment, and antiretroviral prophylaxis adherence of South African rape survivors. *J Acquir Immune Defic Syndr.* 2007;46(1):68-71.

86. Abrahams N, Jewkes R, Lombard C, Mathews S, Campbell J, Meel B. Impact of telephonic psycho-social support on adherence to post-exposure prophylaxis (PEP) after rape. *AIDS.* 2010;22(10):1173-1181.

87. Roland ME, Myer L, Martin LJ, et al. Preventing human immunodeficiency virus infection among sexual assault survivors in Cape Town, South Africa: an observational study. *AIDS Behav.* 2012;16(4):990-998.

88. Wiebe ER, Comay SE, McGregor M, Ducceschi S. Offering HIV prophylaxis to people who have been sexually assaulted: 16 months' experience in a sexual assault service. *CMAJ.* 2000;162(5):641-645.

89. Bani-Sadr F, Teissiere F, Curie I, et al. [Anti-infection prophylaxis after sexual assault. Experience of the Raymond Poincare-Garches Hospital]. *Presse medicale.* 2001;30(6):253-258.

90. Limb S, Kawsar M, Forster GE. HIV post-exposure prophylaxis after sexual assault: the experience of a sexual assault service in London. *Int J STD AIDS.* 2002;13(9):602-605.

91. Masanzu R, Ajayi C, Sibly E, Forster G. Post-exposure prophylaxis following sexual assault. *HIV Med.* 2010;11(Suppl. 1):53.

92. Lunding S, Katzenstein TL, Kronborg G, et al. The Danish PEP registry: experience with the use of postexposure prophylaxis (PEP) following sexual exposure to HIV from 1998 to 2006. *Sex Transm Dis.* 2010;37(1):49-52.

93. Garcia MT, Figueiredo RM, Moretti ML, Resende MR, Bedoni AJ, Papaiordanou PMO. Postexposure prophylaxis after sexual assaults: a prospective cohort study. *Sex Transm Dis.* 2005;32(4):214-219.

94. Lacombe K, Daguenel-Nguyen A, Lebeau V, Fonquernie L, Girard PM, Meyohas MC. Determinants of adherence to non-occupational post HIV exposure prophylaxis. *AIDS.* 2006;20(2):291-294.

95. Diniz NM, de Almeida LC, dos S. Ribeiro BC, de Macêdo VG. Women victims of sexual violence: adherence to chemoprevention of HIV. *Rev Lat Am Enfermagem.* 2007;15(1):6.

96. Kim JC, Askew I, Muvhango L, et al. Comprehensive care and HIV prophylaxis after sexual assault in rural South Africa: the Refentse Intervention Study. *BMJ.* 2009;338:b515.

97. MacDonald R. HIV post-exposure prophylaxis prescribing after sexual assault in a sexual assault referral centre. *HIV Med.* 2010;11(Suppl 1):51.

98. Henry K, Acosta EP. Hepatotoxicity and rash associated with zidovudine and zalcitabine chemoprophylaxis. *Ann Intern Med.* 1996;124(9):855-855.

99. Centers for Disease Control and Prevention (CDC). Serious adverse events attributed to nevirapine regimens for postexposure prophylaxis after HIV exposures--worldwide, 1997-2000. *Morb Mortal Wkly Rep.* 2001;49(51):1153-1156.

100. Postma MJ, Bos JM, de Jong-van den Berg LTW, Tramarin A, van Bergen JEAM. HIV post-exposure prophylaxis: enhancing its pharmaco-economic profile by discriminate prescribing. *AIDS.* 2002;16(8):1177-1179.

101. Johnson S, Baraboutis JG. Adverse effects associated with use of nevirapine in HIV postexposure prophylaxis for 2 health care workers. *JAMA.* 2000;284(21):2722-2723.

102. National Institutes of Health. *Viramune Drug Label.* Bethesda, MD: US Department of Health and Human Services; 2014: available at http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5ec05500-6333-4bd0-ac83-464fad0d5162.

103. Sonder GJB, Van den Hoek A, Regez RM, et al. Trends in HIV postexposure prophylaxis prescription and compliance after sexual exposure in Amsterdam, 2000-2004. *Sex Transm Dis.* 2007;34(5):288-293.

104. Rhee SY, Blanco JL, Jordan MR, et al. Geographic and temporal trends in the molecular epidemiology and genetic mechanisms of transmitted HIV-1 drug resistance: an individual-patient- and sequence-level meta-analysis. *PloS Med.* 2015;12(4):1-29.

105. Golub SA, Rosenthal L, Cohen DE, Mayer KH. Determinants of high-risk sexual behavior during post-exposure prophylaxis to prevent HIV infection. *AIDS Behav.* 2008;12(6):852-859.

106. Martin JN, Roland ME, Neilands TB, et al. Use of postexposure prophylaxis against HIV infection following sexual exposure does not lead to increases in high-risk behavior. *AIDS.* 2004;18(5):787-792.

107. Waldo CR, Stall RD, Coates TJ. Is offering post-exposure prevention for sexual exposures to HIV related to sexual risk behavior in gay men? *AIDS.* 2000;14(8):1035-1039.

108. Heuker J, Sonder GJB, Stolte I, Geskus R, van den Hoek A. High HIV incidence among MSM prescribed postexposure prophylaxis, 2000-2009: indications for ongoing sexual risk behaviour. *AIDS.* 2012;26(4):505-512.

109. van Der Snoek EM, de Wit JB, Mulder PG, van Der Meijden WI. Incidence of sexually transmitted diseases and HIV infection related to perceived HIV/AIDS threat since highly active antiretroviral therapy availability in men who have sex with men. *Sex Transm Dis.* 2005;32(3):170-175.

110. Poynten IM, Jin F, Mao L, et al. Nonoccupational postexposure prophylaxis, subsequent risk behaviour and HIV incidence in a cohort of Australian homosexual men. *AIDS.* 2009;23(9):1119-1126.

111. Loke WC, Conway K, Kulasegaram R. The impact of taking HIV post-exposure prophylaxis after sexual exposure (PEPSE) on sexual behaviour. *HIV Med.* 2010;11(Suppl 1):52.

112. Siemieniuk RA, Sivachandran N, Murphy P, et al. Transitioning to HIV pre-exposure prophylaxis (PrEP) from non-occupational post-exposure prophylaxis (nPEP) in a comprehensive HIV prevention clinic: a prospective cohort study. *AIDS Patient Care STDS.* 2015;29(8):431-436.

113. Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration, National Institutes of Health, et al. Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States, 2014. Atlanta, GA: CDC; 2014: available at http://stacks.cdc.gov/view/cdc/26062. Accessed October 9, 2015.

114. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health.; 2014: available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf. Accessed October 5, 2015.

115. Antiretroviral Pregnancy Registry Steering Committee. Antiretroviral Pregnancy Registry International Interim Report for 1 January 1989 through 31 July 2014. Wilmington, NC: Registry Coordinating Center; 2014: available at http://www.apregistry.com/forms/interim_report.pdf. Accessed October 5, 2015.

116. Unadkat JD, Wara DW, Hughes MD, et al. Pharmacokinetics and safety of indinavir in human immunodeficiency virus-infected pregnant women. *Antimicrob Agents Chemother.* 2007;51(2):783-786.

117. Hayashi S, Beckerman K, Homma M, Kosel BW, Aweeka FT. Pharmacokinetics of indinavir in HIV-positive pregnant women. *AIDS.* 2000;14(8):1061-1062.

118. Food and Drug Administration (FDA). Sustiva: prescribing information. Rockville, MD: US Department of Health and Human Services, FDA; 2010: available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/02136s024lbl.pdf. Accessed October 9, 2015.

119. Brogly SB, Abzug MJ, Watts DH, et al. Birth defects among children born to human immunodeficiency virus-infected women: pediatric AIDS clinical trials protocols 219 and 219C. *Pediatr Infect Dis J.* 2010;29(8):721-727.

120. Knapp KM, Brogly SB, Muenz DG, et al. Prevalence of congenital anomalies in infants with in utero exposure to antiretrovirals. *Pediatr Infect Dis J.* 2012;31(2):164-170.

121. Ford N, Mofenson L, Shubber Z, et al. Safety of efavirenz in the first trimester of pregnancy: an updated systematic review and meta-analysis. *AIDS.* 2014;28 Suppl 2:S123-131.

122. Peters PJ, Stringer J, McConnell MS, et al. Nevirapine-associated hepatotoxicity was not predicted by CD4 count >= 250 cells/mu L among women in Zambia, Thailand and Kenya. *HIV Med.* 2010;11(10):650-660.

123. Mandelbrot L, Kermarrec N, Marcollet A, et al. Case report: nucleoside analogue-induced lactic acidosis in the third trimester of pregnancy. *AIDS.* 2003;17(2):272-273.

124. Luzzati R, Del Bravo P, Di Perri G, Luzzani A, Concia E. Riboflavine and severe lactic acidosis. *Lancet.* 1999;353(9156):901-902.

125. Centers for Disease Control and Prevention. Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention. 2015; http://www.cdc.gov/hiv/prevention/research/compendium/index.html. Accessed December, 15, 2015.

126. Roland ME, Neilands TB, Krone MR, et al. A randomized noninferiority trial of standard versus enhanced risk reduction and adherence counseling for individuals receiving post-exposure prophylaxis following sexual exposures to HIV. *Clin Infect Dis.* 2011;53(1):76-83.

127. Landovitz RJ, Fletcher JB, Shoptaw S, Reback CJ. Contingency management facilitates the use of postexposure prophylaxis among stimulant-using men who have sex with men. *Open Forum Infect Dis.* 2015;2(1):1-9.

128. Ford N, Irvine C, Shubber Z, et al. Adherence to HIV postexposure prophylaxis: a systematic review and meta-analysis. *AIDS.* 2014;28(18):2721-2727.

129. Pinkerton SD, Martin JN, Roland ME, Katz MH, Coates TJ, Kahn JO. Cost-effectiveness of HIV postexposure prophylaxis following sexual or injection drug exposure in 96 metropolitan areas in the United States. *AIDS.* 2004;18(15):2065-2073.

130. Pinkerton SD, Martin JN, Roland ME, Katz MH, Coates TJ, Kahn JO. Cost-effectiveness of postexposure prophylaxis after sexual or injection-drug exposure to human immunodeficiency virus. *Arch Intern Med.* 2004;164(1):46-54.

131. Gerberding JL, Katz MH. Post-exposure prophylaxis for HIV. In: Mills J, Volberding PA, Corey L, eds. *Antiviral Chemotherapy 5: New Directions for Clinical Application and Research.* Vol 45. New York, NY: Springer; 1999:213-222.

132. Royce RA, Sena A, Cates W, Jr., Cohen MS. Sexual transmission of HIV. *New Engl J Med.* 1997;336(15):1072-1078.

133. Vittinghoff E, Douglas J, Judson F, McKirnan D, MacQueen K, Buchbinder SP. Per-contact risk of human immunodeficiency virus transmission between male sexual partners. *Am J Epidemiol.* 1999;150(3):306-311.

134. Holmberg SD. The estimated prevalence and incidence of HIV in 96 large US metropolitan areas. *Am J Public Health.* 1996;86(5):642-654.

135. Guinot D, Ho MT, Poynten IM, et al. Cost-effectiveness of HIV nonoccupational post-exposure prophylaxis in Australia. *HIV Med.* 2009;10(4):199-208.

136. Herida M, Larsen C, Lot F, Laporte A, Desenclos JC, Hamers FF. Cost-effectiveness of HIV post-exposure prophylaxis in France. *AIDS.* 2006;20(13):1753-1761.

137. Katz MH, Gerberding JL. The care of persons with recent sexual exposure to HIV. *Ann Intern Med.* 1998;128(4):306-312.

138. Katz MH, Gerberding JL. Postexposure treatment of people exposed to the human immunodeficiency virus through sexual contact or injection-drug use. *New Engl J Med.* 1997;336(15):1097-1100.

139. Mayer KH, Kwong J, Singal R, Boswell S. Non-occupational postexposure HIV prophylaxis: clinical issues and public health questions. *Med health RI.* 2000;83(7):210-213.

140. Desmond NM, Coker RJ. Should preventive antiretroviral treatment be offered following sexual exposure to HIV? The case for. *Sex Transm Infect.* 1998;74(2):144-145.

141. Desmond NM, King ECJ, Dawson SG. Sexual exposure to HIV infection: Is there a role for emergency prophylaxis? *Int J STD AIDS.* 1998;9(1):51-52.

142. Sultan B, Benn P, Waters L. Current perspectives in HIV post-exposure prophylaxis. *HIV AIDS (Auckl).* 2014;6:147-158.

143. Doblecki-Lewis S, Kolber MA. Preventing HIV infection: pre-exposure and postexposure prophylaxis. *IUBMB life.* 2014;66(7):453-461.

144. Kaplan JE, Dominguez K, Jobarteh K, Spira TJ. Postexposure prophylaxis against human immunodeficiency virus (HIV): new guidelines from the WHO: a perspective. *Clin Infect Dis.* 2015;60 Suppl 3:S196-199.

145. Evans B, Darbyshire J, Cartledge J. Should preventive antiretroviral treatment be offered following sexual exposure to HIV? Not yet! *Sex Trans Infect.* 1998;74(2):146-148.

146. Mackie NE, Coker RJ. Post-exposure prophylaxis following non-occupational exposure to HIV: risks, uncertainties, and ethics. *Int J STD AIDS.* 2000;11(7):424-427.

147. Myles JE, Bamberger JD. *Offering HIV prophylaxis following sexual assault: recommendations for the State of California.* Sacramento, CA: California Department of Health Services;2001.

148. Commonwealth of Massachusetts Department of Public Health. Clinical Advisory: HIV prophylaxis for non-occupational exposures. Boston, MA: Massachusetts Department of Public Health; 2000: Available at http://www.mass.gov/dph/aids/guidelines/ca_exposure_nonwork.htm

149. Landovitz RJ, Combs KB, Currier J. Availability of HIV post-exposure prophylaxis services in Los Angeles County *Clin Infect Dis.* 2009;48(11):1624-1627.

150. Fitzpatrick LJ, Egan DJ, Cowan E, et al. Nonoccupational post-exposure prophylaxis for HIV in New York State emergency departments. *J Int Assoc Provid AIDS Care.* 2014;13(6):539-546.

151. Rodriguez AE, Castel AD, Parish CL, et al. HIV medical providers' perceptions of the use of antiretroviral therapy as nonoccupational postexposure prophylaxis in 2 major metropolitan areas. *J Acquir Immune Defic Syndr.* 2013;64 Suppl 1:S68-79.

152. Kearney S, Sharathkumar A, Rodriguez V, et al. Neonatal circumcision in severe haemophilia: a survey of paediatric haematologists at United States Hemophilia Treatment Centers. *Haemophilia.* 2015;21(1):52-57.

153. Draughon JE, Anderson JC, Hansen BR, Sheridan DJ. Nonoccupational postexposure HIV prophylaxis in sexual assault programs: a survey of SANE and FNE program coordinators. *J Assoc Nurses AIDS Care.* 2014;25(1 Suppl):S90-S100.

154. Kahn JO, Martin JN, Roland ME, et al. Feasibility of postexposure prophylaxis (PEP) against human immunodeficiency virus infection after sexual or injection drug use exposure: the San Francisco PEP Study. *J Infect Dis.* 2001;183(5):707-714.

155. Patel P, Borkowf CB, Brooks JT, Lasry A, Lansky A, Mermin J. Estimating per-act HIV transmission risk: a systematic review. *AIDS.* 2014;28(10):1509-1519.

156. Abdala N, Reyes R, Carney JM, Heimer R. Survival of HIV-1 in syringes: effects of temperature during storage. *Substance Use Misuse.* 2000;35(10):1369-1383.

157. Rich JD, Dickinson BP, Carney JM, Fisher A, Heimer R. Detection of HIV-1 nucleic acid and HIV-1 antibodies in needles and syringes used for non-intravenous injection. *AIDS.* 1998;12(17):2345-2350.

158. Richman KM, Rickman LS. The potential for transmission of human immunodeficiency virus through human bites. *J Acquir Immune Defic Syndr.* 1993;6(4):402-406.

159. Anonymous. Transmission of HIV by a human bite. *Lancet.* 1987;2(8557):522.

160. Vidmar L, Poljak M, Tomazic J, Seme K, Klavs I. Transmission of HIV-1 by human bite. *Lancet.* 1996;347(9017):1762-1763.

161. Deshpande AK, Jadhav SK, Bandivdekar AH. Possible transmission of HIV infection due to human bite. *AIDS Res Ther.* 2011;8(1):16.

162. Andreo SMS, Barra LAC, Costa LJ, Sucupira MCA, Souza IEL, Diaz RS. Short communication: HIV type 1 transmission by human bite. *AIDS Res Hum Retroviruses.* 2004;20(4):349-350.

163. Pilcher CD, Eron JJ, Jr., Vemazza PL, et al. Sexual transmission during the incubation period of primary HIV infection. *JAMA.* 2001;286(14):1713-1714.

164. Chakraborty H, Sen PK, Helms RW, et al. Viral burden in genital secretions determines male-to-female sexual transmission of HIV-1: a probabilistic empiric model. *AIDS.* 2001;15(5):621-627.

165. Hirsch MS, Günthard HF, Schapiro JM, et al. Antiretroviral drug resistance testing in adult HIV-1 infection: 2008 recommendations of an International AIDS Society-USA panel. *Clin Infect Dis.* 2008;47(2):266-285.

166. Ridzon R, Gallagher K, Ciesielski C, et al. Simultaneous transmission of human immunodeficiency virus and hepatitis C virus from a needle-stick injury. *N Engl J Med.* 1997;336(13):919-922.

167. Ciesielski CA, Metler RP. Duration of time between exposure and seroconversion in healthcare workers with occupationally acquired infection with human immunodeficiency virus. *Am J Med.* 1997;102(5B):115-116.

168. Hecht FM, Busch MP, Rawal B, et al. Use of laboratory tests and clinical symptoms for identification of primary HIV infection. *AIDS.* 2002;16(8):1119-1129.

169. Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. *Curr Opin HIV AIDS.* 2008;3(1):10-15.

170. Vanhems P, Routy JP, Hirschel B, et al. Clinical features of acute retroviral syndrome differ by route of infection but not by gender and age. *J Acquir Immune Defic Syndr.* 2002;31(3):318-321.

171. Rich JD, Merriman NA, Mylonakis E, et al. Misdiagnosis of HIV infection by HIV-1 plasma viral load testing: A case series. *Ann Intern Med.* 1999;130(1):37-39.

172. Puro V, Calcagno G, Anselmo M, et al. Transient detection of plasma HIV-1 RNA during postexposure prophylaxis. *Infect Control and Hosp Epidemiol.* 2000;21(8):529-531.

173. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Bethesda, MD: Department of Health and Human Services, National Institutes of Health 2015: Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf Accessed October 6, 2015.

174. Workowski KA, Bolan G. Sexually Transmitted Diseases Treatment Guidelines. *MMWR Recomm Rep.* Vol 64. Atlanta: Centers for Disease Control and Prevention; 2015: available at http://www.cdc.gov/std/tg2015/tg-2015-print.pdf. Accessed October 6, 2015.

175. Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *C. trachomatis* and *N. gonorrhoeae* — 2014. 2014; http://www.cdc.gov/std/laboratory/2014labrec/recommendations2.htm. Accessed January 13, 2016.

176. Centers for Disease Control and Prevention (CDC). Recommendations for Routine Testing and Follow-Up for Chronic Hepatitis B Virus (HBV) Infection. Atlanta, GA: US Department of Health and Human Services, CDC; 2008: available at http://www.cdc.gov/hepatitis/hbv/PDFs/ChronicHepBTestingFlwUp.pdf. Accessed October 6, 2015.

177. Centers for Disease Control and Prevention (CDC). Hepatitis B FAQs for Health Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2015: available at http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm#general.

178. Mugo NR, Heffron R, Donnell D, et al. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS.* 2011;25(15):1887-1895.

179. Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health; 2015: available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf. Accessed October 6, 2015.

180. Chaudry NI, Eron JJ, Naderer OJ, et al. Effects of formulation and dosing strategy on amprenavir concentrations in the seminal plasma of human immunodeficiency virus type 1-infected men. *Clin Infect Dis.* 2002;35(6):760-762.

181. Reddy YS, Gotzkowsky SK, Eron JJ, et al. Pharmacokinetic and pharmacodynamic investigation of efavirenz in the semen and blood of human immunodeficiency virus type 1-infected men. *J Infect Dis.* 2002;186(9):1339-1343.

182. Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: implications for prevention of HIV-1 transmission. *Sci Transl Med.* 2011;3(112):1-8.

183. Food and Drug Adminstration (FDA). Information for health care professional: Abacavir (marketed as Ziagen) and abacavir-containing medications. Rockville, MD: US Department of Health and Human Services, FDA; 2013: available at http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm123927.htm. Accessed October 8, 2015.

184. Ford N, Venter F, Irvine C, Beanland RL, Shubber Z. Starter packs versus full prescription of antiretroviral drugs for postexposure prophylaxis: a systematic review. *Clin Infect Dis.* 2015;60 Suppl 3:S182-186.

185. Chandwani S, Koenig LJ, Sill AM, Abramowitz S, Conner LC, D'Angelo L. Predictors of antiretroviral medication adherence among a diverse cohort of adolescents with HIV. *J Adolescent Health.* 2012;51(3):242-251.

186. Koenig LJ, Lyles C, Smith DK. Adherence to antiretroviral medications for HIV pre-exposure prophylaxis: lessons learned from trials and treatment studies. *Am J Prev Med.* 2013;44(1 (S2)):S91-S97.

187. Peterson J, Di Clemente R. *The Handbook of HIV Prevention.* New York, NY: Kluwer Academic/Plenum; 2000.

188. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis.* 2014;14(9):820-829.

189. Black MC, Basile KC, Breiding MJ, et al. The National Intimate Partner and Sexual Violence Survey (NISVS): 2010 Summary Report Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2011: Available at http://www.cdc.gov/violenceprevention/pdf/nisvs_report2010-a.pdf. Accessed October 8, 2015.

190. Lipscomb GH, Muram D, Speck PM, Mercer BM. Male victims of sexual assault. *JAMA.* 1992;267(22):3064-3066.

191. Riggs N, Houry D, Long G, Markovchick V, Feldhaus KM. Analysis of 1,076 cases of sexual assault. *Ann Emerg Med.* 2000;35(4):358-362.

192. Swan H, O'Connell DJ. The impact of intimate partner violence on women's condom negotiation efficacy. *J Interpers Violence.* 2012;27(4):775-792.

193. Raj A, Santana MC, La Marche A, Amaro H, Cranston K, Silverman JG. Perpetration of intimate partner violence associated with sexual risk behaviors among young adult men. *Am J Public Health.* 2006;96(10):1873-1878.

194. Wingood GM, DiClemente RJ, Raj A. Adverse consequences of intimate partner abuse among women in non-urban domestic violence shelters. *Am J Prev Med.* 2000;19(4):270-275.

195. Wingood GM, DiClemente RJ, Raj A. Identifying the prevalence and correlates of STDs among women residing in rural domestic violence shelters. *Women Health.* 2000;30(4):15-26.

196. Gielen AC, Ghandour RM, Burke JG, Mahoney P, McDonnell KA, O'Campo P. HIV/AIDS and intimate partner violence—Intersecting women's health issues in the United States. *Trauma Violence Abuse.* 2007;8(2):178-198.

197. Campbell JC, Soeken K. Forced sex and intimate partner violence: effects on women's health *Violence Against Women.* 1999;5:1017-1035.

198. Digiovanni C, Berlin F, Casterella P, et al. Prevalence of HIV antibody among a group of paraphilic sex offenders. *J Acquir Immune Defic Syndr.* 1991;4(6):633-637.

199. Bristol-Myers Squibb. Efavirenz (Sustiva) [package insert]. New York, NY: Bristol-Myers Squibb; 2015: available at http://packageinserts.bms.com/pi/pi_sustiva.pdf. Accessed October 8, 2015.

200. Wohl AR, Johnson D, Jordan W, et al. High-risk behaviors during incarceration in African-American men treated for HIV at three Los Angeles public medical centers. *J Acquir Immune Defic Syndr.* 2000;24(4):386-392.

201. Mutter RC, Grimes RM, Labarthe D. Evidence of intraprison spread of HIV infection. *Arch Intern Med.* 1994;154(7):793-795.

202. Brewer TF, Vlahov D, Taylor E, Hall D, Munoz A, Polk BF. Transmission of HIV-1 within a statewide prison system. *AIDS.* 1988;2(5):363-367.

203. Gupta N, Schmidt H, Buisker T, et al. After the fact: a brief educational program on HIV postexposure prophylaxis for female detainees in a local jail. *J Correct Health Care.* 2015;21(2):140-151.

204. Federal Bureau of Prisons. Medical Management of Exposures: HIV, HBV, HCV, Human Bites, and Sexual Assaults. Bureau of Prisons Clinical Practice Guidelines, March 2014. Washington, DC: US Department of Justice, Federal Bureau of Prisons; 2014: available at http://www.bop.gov/resources/pdfs/exposures.pdf. Accessed October 8, 2015.

205. Gruber VA, McCance-Katz EF. Methadone, buprenorphine, and street drug interactions with antiretroviral medications. *Curr HIV/AIDS Rep.* 2010;7(3):152-160.

206. Lehman JS, Carr MH, Nichol AJ, et al. Prevalence and public health implications of state laws that criminalize potential HIV exposure in the United States. *AIDS Behav.* 2014;18(6):997-1006.

207. Culp L, Caucci L. State adolescent consent laws and implications for pre-exposure prophylaxis (PrEP). *Am J Prev Med.* 2012;44(1S2):S119-S124.

Appendix 1A

Summary of Methods for nPEP Guidelines Development and Roles of Teams and Consultants

Topic	Comment
The guidelines' goal	Provide guidance for medical practitioners regarding nPEP use for persons in the United States.
nPEP Working Group	The nPEP Working Group is composed of 13 members from the Centers for Disease Control and Prevention (CDC) with expertise in nPEP or other subject areas pertinent to the guidelines (e.g., cost-effectiveness, sexual assault, or nPEP adherence), including certain members who were involved in the writing of the previous version(s) of the CDC nPEP guidelines.
nPEP Writing Group	The nPEP Writing Group is composed of 12 members from CDC with expertise in nPEP or other subject areas pertinent to the guidelines (e.g., cost-effectiveness, sexual assault, or nPEP adherence, etc.), including 1 member who was involved in the writing of the previous version of CDC's nPEP guidelines.
nPEP external consultants	External consultants were selected from government, academia, and the health care community by CDC to participate in 2 consultations by telephone conference call regarding nPEP on the basis of the member's area of subject matter expertise. Each consultation was chaired by 1 of the CDC nPEP co-chairs. The list of the external consultants is available in Appendix 2B.
Competing interests and management of conflicts of interest	All internal CDC staff and external consultants involved in developing the guidelines or who served in the external consultations submitted a written financial disclosure statement reporting any potential conflicts of interest related to questions discussed during the consultations or concerns involved in developing of the nPEP guidelines. A list of these disclosures and their last update is available in Appendix 2C. The nPEP co-chairs reviewed each reported association for potential competing interest and determined the appropriate action, as follows: disqualification from the panel, disqualification/recusal from topic review and discussion; or no disqualification needed. A *competing interest* is defined as any direct financial interest related to a product addressed in the section of the guideline to which a panel member contributes content. *Financial interests* include direct receipt by the panel member of payments, gratuities, consultancies, honoraria, employment, grants, support for travel or accommodation, or gifts from an entity having a commercial interest in that product. *Financial interest* also includes direct compensation for membership on an advisory board, data safety monitoring board, or speakers bureau. Compensation and support that filters through a panel member's university or institution (e.g., grants or research funding) is not considered a competing interest.

3250

Topic	Comment
OMB Peer Review and OMB Public Engagement	As recommended by the Office of Management and Budget for scientific documents fitting the classification of Influential Scientific Information, during Oct. 2014–December 2015, the draft nPEP guidelines underwent peer review by independent scientific and technical experts. They were asked to review the scientific and technical evidence that provides the basis for the nPEP guidelines and to provide input on the draft guidelines before they were finalized. Peer reviewers were asked whether any recommendations are based on studies that were inappropriate as supporting evidence or were misinterpreted, whether there are significant oversights, omissions, or inconsistencies that are critical for the intended audience of clinicians, and whether the recommendations for the intended audience of health care providers are justified and appropriate. In addition, the recommendations from the draft nPEP guidelines were presented to the public through 2 public engagement webinars on November 14 and 17, 2014. Based on the responses from both peer review and public engagement, updates were made to the nPEP guidelines prior to their publication. CDC's responses to the comments were also posted on the CDC/ATSDR Peer Review Agenda website at http://www.cdc.gov/od/science/quality/support/peer-review.htm and the CDC Division of HIV/AIDS Prevention Program Planning Scientific Information Quality—Peer Review Agenda website at http://www.cdc.gov/hiv/policies/planning.html.
Guidelines users	Health care providers
Developer	The CDC nPEP Working Group
Funding source	Epidemiology Branch, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention, CDC
Recommendation ratings	Because none of the evidence is based on randomized clinical trials, but rather observational studies or expert opinion, we have elected not to provide graded recommendations for these guidelines.
Abbreviations: AIDS, acquired immunodeficiency virus; CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis.	

3251

Appendix 1B

nPEP Guidelines Development Teams and Consultants

CDC nPEP Guidelines Writing Team

Kenneth L. Dominguez, MD, MPH (lead author), Dawn K. Smith, MD, MS, MPH, Vasavi Thomas, RPh, MPH; Nicole Crepaz, PhD; Karen S. Lang, MSW; Walid Heneine, PhD; Janet McNicholl, MD; Laurie Reid, RN, MS; Brandi Freelon, MD; Steven Nesheim, MD; Ya-lin (Aileen) Huang, PhD; and Paul J. Weidle, PharmD, MPH.

CDC nPEP Working Group

Ken Dominguez, MD, MPH (Co-lead); Vasavi Thomas, RPh, MPH (Co-lead), Dawn K. Smith, MD, MS, MPH; Steve Nesheim, MD; Walid Heneine, PhD; Lauri Reed, Brandi Freelon, MD; Nicole Crepaz, PhD; Karen S. Lang, MSW; Ya-lin (Aileen) Huang, PhD; Kathleen Irwin, MD, MPH; Gema Dumitru, MD; David Kuhar, MD; and Lynn Paxton, MD, MPH.

Federal Consultants

CDC: Norma Harris, PhD; John Brooks, MD; Pragna Patel, MD, MPH; and Philip J. Peters, MD.

Other Federal Agencies

Holly Van Lew, PharmD, Indian Health Service; Newton Kendig, MD, Bureau of Prisons; David Burns, MD, National Institutes of Health; Laura Cheever, MD, Health Resources and Services Administration; Maggie Czarnogorski, MD, Department of Veterans Affairs; Heather Huentelman, PharmD, Indian Health Service; Kimberly Struble, PharmD, Food and Drug Administration; Rohan Hazra, MD, National Institutes of Health; Lynne Mofenson, MD, National Institutes of Health; and Steve George Siberry, MD, MPH, National Institutes of Health.

Nonfederal External Consultants

Jeffrey Beal, MD, Florida Department of Health; Ronald H. Goldschmidt, MD, University of California, San Francisco; Donna Greco, MSW, Pennsylvania Coalition Against Rape/National Sexual Violence Resource Center; Angela Kashuba, BScPhm, PharmD, University of Northern Carolina Center for AIDS Research, Chapel Hill; Sally Laskey, MA, National Sexual Violence Resource Center, Enola, Pennsylvania; Kenneth Mayer, MD, Fenway Health Center, Boston, Massachusetts; Thera Meehan, MS, MPH, Massachusetts Department of Public Health, Boston; Jennifer Sayles, MD, Los Angeles County Public Health Department, California; Barbara Sheaffer, MA, Pennsylvania Coalition Against Rape, Enola, Pennsylvania; Lyn Stevens, MS, ACRN, NP, New York State Department of Health, Albany; Elaine Abrams, MD, Columbia University College of Physicians & Surgeons, New York, New York; Michael Brady, MD, Columbus Children's Hospital, Ohio; Ellen Chadwick, MD, Northwestern University's Feinberg School of Medicine, Chicago, Illinois; Rana Chakraborty, MD, Emory University School of Medicine, Atlanta, Georgia; Ellen Cooper, MD, Boston University School of Medicine, Massachusetts; Peter Havens, MD, MPH, Children's Hospital of Wisconsin, Milwaukee; Daniel Johnson, MD, Comer Children's Hospital, University of Chicago, Illinois; Paul Krogstad, MD, University of California at Los Angeles–David Geffen School of Medicine; Natalie Neu, MD, MPH, Columbia University Medical Center, New York, New York; Vicki Peters, MD, New York City Department of Health and Mental Hygiene, New York; Russ van Dyke, MD, Tulane University School of Medicine. New

Orleans, Louisiana; and Geoffrey Weinberg, MD, University of Rochester Medical Center, School of Medicine and Dentistry, New York.

CDC Scientific Support Staff

Beverly Bohannon, RN, MS; and Wayne Hairston II, MPH, MBA, ICF International, Atlanta, Georgia.

CDC editor

C. Kay Smith, Med

Abbreviation: nPEP, nonoccupational postexposure prophylaxis.

Appendix 1C

Financial Disclosures of Potential Competing Interest nPEP Guidelines Consultants and Working Group

Member (affiliation)	Role	Company	Relationship	Determination
Elaine Abrams, MD, Columbia University College of Physicians & Surgeons	Non-federal external consultant	None		
Jeffrey Beal, MD, Florida Department of Health	Non-federal external consultant	CDC Flow Through Money—Perinatal Transmission Project	Principal Investigator	No disqualification needed
Beverly Bohannon, RN, MS, CDC	CDC scientific support staff	None		
Michael Brady, MD, Columbus Children's Hospital	Non-federal external consultant	None		
John Brooks, MD, CDC	Other CDC consultant	None		
David Burns, MD, NIH	Other federal consultant	None		
Ellen Chadwick, MD, Northwestern University's Feinberg School of Medicine	Non-federal external consultant	Abbott Labs	Spouse—Abbott retiree; Spouse—owner of stocks and stock options	Recusal from topic review and discussion of selection of antiretrovirals for nPEP use
Rana Chakraborty, MD, Emory University School of Medicine	Non-federal external consultant	None		
Laura Cheever, MD, HRSA	Other federal consultant	None		
Ellen Cooper, MD, Boston University School of Medicine	Non-federal external consultant	None		
Nicole Crepaz, PhD, CDC	nPEP Writing Team, nPEP Workgroup	None		
Maggie Czarnogorski, MD, Department of Veterans Affairs	Other federal consultant	None		
Kenneth L. Dominguez, MD, MPH, Co-lead, CDC	nPEP Writing Team and nPEP Workgroup (co-lead)	None		
Gema Dumitru, MD, CDC	nPEP Workgroup	None		
Brandi Freelon, MD, CDC	nPEP Writing Team and nPEP Workgroup	None		
Ronald H. Goldschmidt, MD, University of California, San Francisco	Non-federal external consultant	CDC funding PEPline	Director—National HIV/AIDS Clinician's Consultation Center	No disqualification needed
Wayne Hairston II, MPH, MBA, CDC	CDC scientific support staff	None		
Norma Harris, PhD, CDC	Other CDC consultant	None		

Member (affiliation)	Role	Company	Relationship	Determination
Peter Havens, MD, MPH, Children's Hospital of Wisconsin	Non-federal external consultant	None		
Rohan Hazra, MD, NIH	Other federal consultant	None		
Walid Heneine, PhD, CDC	nPEP Writing Team and nPEP Workgroup	None		
Ya-lin (Aileen) Huang, PhD, CDC	nPEP Writing Team and nPEP Workgroup	None		
Heather Huentelman, PharmD, IHS	Other federal consultant	None		
Kathleen Irwin, MD, MPH, CDC	nPEP Workgroup	None		
Daniel Johnson, MD, Comer Children's Hospital; University of Chicago	Non-federal external consultant	None		
Angela Kashuba, BScPhm, PharmD, University of North Carolina Center for AIDS Research	Non-federal external consultant	None		
Newton Kendig, MD, Bureau of Prisons	Other federal consultant			
Paul Krogstad, MD, University of California Los Angeles—David Geffen School of Medicine	Non-federal external consultant	None		
David Kuhar, MD, CDC	nPEP Workgroup	None		
Karen S. Lang, MSW, CDC	nPEP Writing Team and nPEP Workgroup	None		
Sally Laskey, MA, National Sexual Violence Resource Center	Non-federal external consultant	None		
Janet McNicholl, MD, CDC	nPEP Writing Team	None		
Thera Meehan, MS, MPH, Massachusetts Department of Public Health	Non-federal external consultant	None		
Lynne Mofenson, MD, NIH	Other federal consultant	None		
Steven Nesheim, MD, CDC	nPEP Writing Team and nPEP Workgroup	None		
Natalie Neu, MD, MPH, Columbia University Medical Center	Non-federal external consultant	None		
Pragna Patel, MD, CDC	Other CDC consultant	None		
Lynn Paxton, MD, MPH, CDC	nPEP Workgroup	None		
Philip J. Peters, MD, CDC	Other CDC consultant	None		
Vicki Peters, MD, New York City Department of Health and Mental Hygiene	Non-federal external consultant	None		

Member (affiliation)	Role	Company	Relationship	Determination
Laurie Reid, RN, MS, CDC	nPEP Writing Team and nPEP Workgroup	None		
Jennifer Sayles, MD, Los Angeles County Public Health Department	Non-federal external consultant	None		
Barbara Sheaffer, MA, Pennsylvania Coalition Against Rape	Non-federal external consultant	CDC funding—National Sexual Violence Resource Center	Medical Advocacy Coordinator	No disqualification needed
George Steve Siberry, MD, MPH, NIH	Other federal consultant	None		
Dawn Smith, MD, MS, MPH, CDC	nPEP Writing Team and nPEP Workgroup	Salaried by CDC to do nPEP work	Medical Epidemiologist, Biologic Intervention	No disqualification needed
Lyn Stevens, MS, ACRN, NP, New York State Department of Health	Non-federal external consultant	CDC Grant (Adult Viral Hepatitis)	Adult Viral Hepatitis Prevention Coordinator	No disqualification needed
Kimberly Struble, PharmD, FDA	Other federal consultant	None		
Vasavi Thomas, RPh, MPH, CDC	nPEP Writing Team and nPEP Workgroup (co-lead)	None		
Russ van Dyke, MD, Tulane University School of Medicine	Non-federal external consultant	None		
Holly Van Lew, PharmD, Indian Health Service	Other federal consultant	None		
Paul J Weidle, PharmD, MPH, CDC	nPEP Writing Team	None		
Geoffrey Weinberg, MD, University of Rochester Medical Center, School of Medicine and Dentistry	Non-federal external consultant	None		

Abbreviations: CDC, Centers for Disease Control and Prevention; nPEP, nonoccupational postexposure prophylaxis.

Appendix 2

Literature Search Methods for the nPEP Guidelines

Topic	Databases	Research Question	Keywords	Dates of Search	Search Limits
Animal Studies	PubMed	Which studies related to PEP involving animal models were published since 2005?	SIV post exposure prophylaxis, post-exposure prophylaxis, antiretroviral prophylaxis in macaques	January 2005 to July 2015	No limitations
Observational Studies, Case Reports	Web of Knowledge, PubMed, Google Scholar	Which are the results of latest nPEP observational and case studies since 2005 with a focus on populations studied, drug regimens used, completion rates, side effects of medications, number of breakthrough infections?	nPEP, nonoccupational postexposure or post-exposure prophylaxis, and HIV postexposure or post-exposure prophylaxis	January 2005 to July 2015	Excluded opinion pieces; no other limitations
Effects on Risk-Reduction Behaviors	MEDLINE, EMBASE, CINAHI [EBSCOhost]	What are the potential behavioral implications of offering nPEP?	HIV infections, acquired immune deficiency syndrome, seropositivity, serodiagnosis, HIV, AIDS, post exposure or post-exposure prophylaxis, post exposure or post-exposure prevention, non-occupational, non pep, NOPEP, nPEP, PEP	January 1996 to July 2015	No limitations
Cost Effectiveness	PubMed	The cost-effectiveness evaluation of nPEP in the United States and other resource-rich countries.	HIV, post exposure post-exposure prophylaxis, PEP, nPEP, economic evaluation, cost utility, cost-benefit analysis, cost benefit, cost effectiveness	January 2005 to July 2015	English only; excluded occupational exposure; not an economic evaluation; no other limitations
Pregnant Women, Women of Childbearing Potential	PubMed	Which nPEP studies involving pregnant women and women of childbearing potential were conducted since 2005?	pregnant women, women of reproductive age, PEP, nPEP, postexposure or post-exposure HIV prophylaxis	January 2005 to July 2015	No limitations
Children/Adolescents	PubMed	Which nPEP studies involving children or adolescents were conducted since 2005?	Children, pediatrics, adolescents, PEP, nPEP, postexposure or post-exposure HIV prophylaxis	January 2005 to July 2015	No limitations
Sexual Assault Survivors	PubMed	Which nPEP studies involving sexual assault survivors were conducted since 2005?	Sexual assault, sexual abuse, PEP, nPEP, postexposure or post-exposure HIV prophylaxis	January 2005 to July 2015	No limitations
Incarcerated Populations	PubMed	Which nPEP studies involving incarcerated populations were conducted since 2005?	Incarcerated, jail, prison, correctional facility, nPEP, PEP	January 2005 to July 2015	No limitations

Abbreviations: AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; nPEP, non-PEP, or NOPEP, nonoccupational postexposure prophylaxis; PEP, postexposure prophylaxis.

3257

Appendix 3

Studies Reviewed for the nPEP Guidelines

MSM Studies

Authors, year: Donnell et al, 2010[14]

Type of study: Randomized behavioral intervention trial to assess perceptions and nPEP use over a 4-year period

Location: 6 U.S. cities

Sample size: n=4,295 MSM

Risk: HIV uninfected men who reported unprotected anal sex in the past year

Intervention: Behavioral intervention vs. standard risk-reduction counseling (accompanying nPEP drug regimen not reported)

Drug regimen: Not reported

Time from exposure to nPEP: Not reported

Completion of nPEP: Not reported

HIV seroconversions: 3

Conclusion: Increased odds of nPEP use was observed in participants with multiple partners and participants who had unprotected anal sex with HIV infected and unknown status partners. The availability of nPEP did not lead to an increase in high-risk sex.

Authors, year: Foster et al, 2015[19]

Type of study: Open-label, single-arm nonrandomized trial at 2 public sexual health clinics and 2 hospital EDs during December 23, 2012–June 12, 2014.

Location: Melbourne, and Sydney, Australia

Sample size: n=100 MSM

Risk: Sexual 65% failed to use a condom after anal intercourse; 29% used a condom but it tore or slipped off; 6% source partner removed condom

Intervention: 3-drug single tablet once daily dose regimen

Drug regimen: RPV + FTC + TDF

Time from exposure to nPEP: ≤72 hours; presentation for nPEP initiation at a mean=30 hours; nPEP initiated at a mean of 2 hours after presentation

Completion of nPEP: 92%

HIV seroconversions: 0 seroconversions occurred through week 12 after initiation of nPEP. Adherence was 98.6% by pill count and 98.5% by self–report; 88% tested had plasma TDF levels suggesting full adherence. 88% experienced ≥1 clinical adverse events. Adverse events included mainly fatigue (34%) and nausea (23%); one participant developed acute abdominal pain and vomiting and grade 4 laboratory evidence of acute pancreatitis ≤1 week of completing nPEP.

Conclusion: A triple ARV regimen of RPV, FTC, and TDF administered once daily as a single combination tablet was well tolerated as nPEP with high levels of adherence and regimen completion.

3258

Authors, year: Jain et al, 2015[18]

Type of study: Retrospective medical record review in a large community health center during July1997–August 2013

Location: Boston, Massachusetts

Sample size: n=788 MSM; median age=32.9 years; 21.2% presented for nPEP 2 or more times (range, 1–15 times)

Risk: Consensual unprotected sex most common n=726 (62.2%); n=425 (58.5%) receptive anal; n=277 (38.2%) insertive anal; n=157 (21.6%) receptive oral intercourse; n=351 (31.1%) condom failure or removal; (35.6%) HIV-positive partner

Intervention: nPEP (number of drugs not reported in this study, however, previous studies from this site have reported 2 or 3 drugs)

Drug regimen: Not reported

Time from exposure to nPEP: Not reported but assume 72 hours based on previously published studies from this site

Completion of nPEP: Not reported

HIV seroconversions: 39 seroconversions occurred at >90 days after initially presenting for nPEP; 4 occurred at <180 days: 91, 133, 160, 168 days; 3 of 4 reported completing 28-day regimen; adherence or ongoing sexual risk behavior not reported; 35 (89.7%) seroconversions occurred at ≥180 days after nPEP initiation; seroconversion associated with younger age and/or being African American or Latino; almost 90% of post-nPEP infections were probably due to subsequent risk-taking and not a failure of the initial nPEP regimen

Conclusion: Younger age, being Latino and/or being African American, but not repeated nPEP use, were associated with incident HIV infection. Younger MSM of color who are nPEP users may benefit from early HIV risk reduction and PrEP.

Authors, year: McAllister et al, 2014[17]

Type of study: Nonrandomized, open-label, prospective cohort study at two urban hospital centers

Location: Sydney, Australia

Sample size: n=125 MSM enrolled; n=91 prescribed 3-drug regimen; n=34 prescribed 2-drug regimen; mean age 32–34 years

Risk: Sexual

Intervention: 2-drug or 3-drug regimen

Drug regimen: TDF + FTC or RAL+ TDF + FTC; Mean Adherence to each arm: TDF + FTC (90%); RAL-FTC-TDF (89%); 8 patients reported myalgia on the 3-drug regimen vs. none on the 2-drug regimen; Grade 4 creatinine kinase elevations occurred in 5 subjects on the 3-drug regimen vs. none on the 2-drug regimen. All Grade 4 creatinine kinase elevations resolved to ≤grade 2 after desisting from exercise and increasing oral fluids intake

Time from exposure to nPEP: Not reported

Completion of nPEP: 86/91 (95%) participants prescribed a 3-drug regimen met criteria to stay on nPEP; 79/86 (92%) completed 28-day 3-drug regimen; 31/34 (91%) participants prescribed 2-drug regimen completed 28-day 2-drug regimen; overall 110/120 (91.7%) who met criteria to stay on nPEP completed 28-day regimen; overall 110/125 (88%) who were prescribed nPEP, completed the 28-day regimen

HIV seroconversions: 0

Conclusion: Although the 3-drug and 2-drug arms had similar percentages of patients completing their 28-day regimens, 9% of the 3-drug arm experienced grade 4 creatinine kinase elevations which subsequently resolved with increased fluid intake and desisting exercise. If a RAL-TDF-FTC regimen is used, a preferred nPEP regimen, authors recommend (1) asking patients about concomitant medications associated with rhabdomyolysis (i.e. statins); (2) patient education about possible association between RAL-containing nPEP, exercise, and rhabdomyolysis and the need to report myalgia; (3) laboratory monitoring of serum creatinine

kinase at baseline; if myalgia or weakness develops, conduct additional during treatment and clinical examination for proximal muscle weakness. Completion rates were higher for this study compared to those in other studies, including similar nPEP regimens. This may have been due to a high level of support provided by the study team including an experienced nPEP nurse, 24-hour contact with the nurse consultant, text reminders of appointments, proactive recall after missed appointments and frequent adherence education.

Authors, year: Schechter et al, 2004[16]

Type of study:

Location: Rio de Janeiro, Brazil

Sample size: n=200 participants; median age, 28 years; n=68 received nPEP

Risk: Sexual exposure (gay or bisexual)

Intervention: 2-drug regimen

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤48 hours

Completion of nPEP: 11 (1 among nPEP users, 10 among patients not using nPEP)

HIV seroconversions:

Conclusion: nPEP was safely tolerated and did not appear to be associated with either increases in reported high-risk behavior or HIV transmission; such findings may limit its impact as a public health intervention

Authors, year: Sonder et al, 2010[15]

Type of study: Observational study comparing 2 nPEP regimens

Location: Amsterdam

Sample size: n=309 MSM

Risk: Sexual exposure

Intervention: One 4-drug regimen and one 3-drug regimen; 2- or 3-pill burden

Drug regimen: Single-dose NVP + ZDV+ 3TC+ NFV or ZDV + 3TC + ATV

Time from exposure to nPEP: Seroconverters presented between 5–36 hours post exposure

Completion of nPEP: 237/261 (91%)

HIV seroconversions: 5 (likely due to ongoing risk behavior)

Conclusion: Common side effects were fatigue, nausea, and diarrhea (worse in regimen 1). There was no significant difference in completion rates of the two regimens. Strategies are needed to prevent subsequent HIV exposures in nPEP-treated individuals

Authors, year: Terzi et al, 2007[13]

Type of study: Case report

Location: Italy

3260

Sample size: n=1 MSM
Risk: Receptive anal intercourse with HIV + male
Intervention: 3-drug regimen; 2-pill burden
Drug regimen: ZDV + 3TC (Combivir) + IDV
Time from exposure to nPEP: 30 hours
Completion of nPEP: Complete adherence
HIV seroconversions:
Conclusion: Sexual exposures to HIV and HCV require prolonged follow-up due to the risk of late seroconversion.

Sexual Assault Studies—Adults, Adolescents, and Children (combined)

Authors, year: Chacko et al, 2012[20]
Type of study: Systematic review of nPEP adherence among victims of sexual assault
Location: U.S. and International
Sample size: n=24 studies of adults, adolescents, and children
Risk: Sexual assault
Intervention: Various 2- and 3-drug regimens
Drug regimen: Most regimens included ZDV
Time from exposure to nPEP: Not reported
Completion of nPEP: 40%
HIV seroconversions: Not reported
Conclusion: Overall adherence was poor but was higher in developing countries compared to developed countries. Common side effects were: nausea and vomiting, diarrhea, and fatigue. More interventions are needed to improve adherence. Standard methods of conducting and reporting nPEP programs are needed.

Authors, year: Draughon and Sheridan, 2011[21]
Type of study: Systematic review spanning 10 years
Location: Sub-Saharan Africa (Kenya, Malawi, and South Africa)
Sample size: n=studies of adults, adolescents, and children
Risk: Sexual assault
Intervention: Not reported
Drug regimen: Not reported
Time from exposure to nPEP: Not reported
Completion of nPEP: 0%–65% (most studies reported >35%)

HIV seroconversions: Not reported

Conclusion: Overall adherence was low, but was higher in locations where the full 28-day PEP regimen was given up front.

Authors, year: Draughon and Sheridan, 2012[22]

Type of study: Systematic review

Location: Low HIV prevalence countries

Sample size: n=34 studies of adults, adolescents, and children

Risk: Sexual assault

Intervention: nPEP (number of drugs not reported by reviewers)

Drug regimen: Not reported

Time from exposure to nPEP: 24–96 hours

Completion of nPEP: 0%–63%

HIV seroconversions: Not reported

Conclusion: There was wide variation in the provision, acceptance, and adherence to nPEP programs. Anywhere from 5%–100% of eligible patients received nPEP across studies. Further research is needed to understand the experience of sexual assault survivors with the health care system and nPEP following an attack

Authors, year: Loutfy et al, 2008[23]

Type of study: Prospective cohort study

Location: Ontario, Canada

Sample size: n=798 sexual assault survivors presented to sexual assault treatment centers and offered nPEP; females (n=775 [97.1%]), age 4–17 years (n=190 [23.8%]), age 18–80 years (n=608 [77.2%]); 347 accepted nPEP

Risk: Sexual assault

Intervention: 3-drug regimen; 2-pill burden

Drug regimen: Combivir + Kaletra

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 111/347 (31.9%) completed nPEP including (11/46 [23.9%]) of participants at high risk completed therapy and (100/301 [33.2%]) of unknown risk participants completed therapy

HIV seroconversions: Not reported

Conclusion: The PEP program for sexual assault survivors in Ontario proved to be feasible and acceptable among participants. The most common side effects were fatigue, nausea, and diarrhea. Further research is needed to improve loss to follow-up and completion rates of nPEP.

Sexual Assault Studies—Adults and/or Adolescents

Authors, year: Carrieri et al, 2006[33]

Type of study: Retrospective survey of nPEP consultations

Location: Southeastern France

Sample size: n=94 persons, aged 18 years or older, presented to AIDS centers for nonoccupational HIV exposure (female n=88 [93.6%], male n=6 [6.4%]); nPEP prescribed to 86 persons

Risk: Sexual assault

Intervention: 2 and 3 drug regimens

Drug regimen: Not reported

Time from exposure to nPEP: 72% (n=77) ≤48 hours

Completion of nPEP: 25% (n=23) >3 months follow-up

HIV seroconversions: Not reported

Conclusion: Half of all participants were lost to follow-up after the first consultation. During the study period there were 600 additional sexual assaults that were reported to police but did not receive nPEP consultation. Prompt HIV medical assessment is needed for sexual assault survivors as well as strategies to improve nPEP adherence.

Authors, year: Griffith et al, 2010[31]

Type of study: Retrospective chart review in an urban county hospital from June 2007–June 2008

Location: Dallas, TX

Sample size: n=151 adolescent and adult women (151 prescribed nPEP, 62 received follow-up of which 58 self-reported taking nPEP); aged 13–17 years, n=43 (28%); 18–61 years, n=108 (72%)

Risk: Sexual assault

Intervention: 3-drug regimen; 2-pill burden

Drug regimen: Kaletra + Truvada or Combivir

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 62/151 (41%) of women presented for a follow-up visit. 37 of the 62 (60%) took nPEP for ≥21 days or completed prescribed course of therapy

HIV seroconversions: 0 (36 of 58 women who reported taking nPEP at follow-up were HIV screened at week 12 or 24 of follow-up)

Conclusion: Full medication compliance and follow-up counseling remain challenges for sexual assault survivors and providers. A detailed nPEP protocol and continuity of care promotes quality patient management.

Authors, year: Krause et al, 2014[34]

Type of study: Retrospective cohort study of medical records from a level 1 trauma center participating in the Sexual Assault Nurse Examiner (SANE) Program

Location: Northeastern, United States

Sample size: n=179 cases of sexual assault among 171 unique female patients, aged ≥16 years (median: 26 years); nPEP offered to 138 patients for whom PEP was appropriate within the 72-hour window period; an additional 5 patients outside the 72-hour window period were offered PEP; 86% or 124/143 cases who were offered PEP, accepted PEP

Risk: Sexual assault

Intervention: 2-drug or 3-drug regimen

Drug regimen: Either FTC/TDF and LPV/r) (n=85, 59.4%) or FTC/TDF alone (n=32, 22.4%)

Time from exposure to nPEP: ≤72 hours (for most cases; 5 cases were given nPEP outside the 72-hour window)

Completion of nPEP: 34 of 124 (27.4%) cases who followed up with an infectious disease specialist completed nPEP

HIV seroconversions: Not reported

Conclusion: All 138 sexual assault case patients who were eligible for nPEP were offered nPEP. Only a minority of those who were documented to have followed up with an infectious disease specialist completed nPEP. There is a need for a better system for post-assault follow-up.

Authors, year: Linden et al, 2005[30]

Type of study: Retrospective medical record review of female sexual assault survivors presenting to an urban ED during 10/1/99–9/30/2002

Location: Boston, MA

Sample size: n=292 charts reviewed; n=181 in final sample size; mean age 29.1 years (range, 18–82); n=89 patients offered nPEP; n=85 patients accepted

Risk: Sexual assault

Intervention: 2-drug or 3-drug regimen; 1- or 2-pill burden

Drug regimen: Initiated in ED, ZDV + 3TC (Combivir) (n=78); Combivir + NFV (n=4); Initiated in referral clinic: 2-drugs (unspecified) (n=2); 3-drugs (unspecified) (n=1)

Time from exposure to nPEP: Median time from assault to presentation in ED (10.1 hours; range, 0–24 hours)

Completion of nPEP: Overall 18 of 85 (21%), including 15 of 82 (18%) of those initiated on nPEP in ED and 3 of 3 initiated on nPEP after being referred to another clinical care site

HIV seroconversions: No seroconversions during follow-up period in 38 patients with at least 1 follow-up visit

Conclusion: A minority of sexual assault survivors were offered nPEP and few completed full nPEP course.

Authors, year: Olshen et al, 2006[32]

Type of study: Retrospective medical record review of adolescents presenting to urban pediatric EDs ≤72 hours of penetrating sexual assault in 2 academic medical centers during July 1, 2001 to June 30, 2003

Location: Boston, MA

Sample size: n=177 adolescents aged 12–22 years; n=145 adolescents with adequate documentation; n=129 eligible for nPEP; n=110 accepted nPEP; n=85 initiated nPEP

Risk: Sexual assault

Intervention: 2-drug or 3-drug regimen

Drug regimen: 3TC + ZDV (94%); 3TC +ZDV + NFV (3%); 3TC + ZDV + IDV (2%)

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 13/85 (15%) who initiated nPEP completed 28-day course; 37 returned for first follow-up visit

HIV seroconversions: No seroconversions among 23 tested for HIV

Conclusion: Poor rates of nPEP completion among adolescent sexual assault survivors. May be due to uncertainties regarding exposure, high rates of psychiatric comorbidity, and low rates of return for follow-up care.

Sexual Assault Studies Including Children and/or Adolescents

Authors, year: Chesshyre et al, 2009[43]

Type of study: Retrospective review of medical records from January 2005–February 2007

Location: Blantyre, Malawi

Sample size: n=217 children and adolescents presented with history of sexual abuse; ages: n=62 (29%)<5 years; n=113 (52%) 5–10 years; n=42 (19%) 11–16 years; n=92 children were eligible for and received nPEP; n=153 children were not offered nPEP because they presented >72 hours or had chronic history of abuse

Risk: Child sexual abuse

Intervention: 2-drug regimen

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: Not reported

HIV seroconversions: No HIV seroconversions in any of the 92 children initiated on nPEP; 7/153 (5%) children who were not offered nPEP tested HIV+

Conclusion: The initiation of an nPEP program for child victims of sexual abuse led to increased numbers of such children presenting for nPEP services and is likely to have resulted in decreased HIV acquisition in this population.

Authors, year: Collings et al, 2008[42]

Type of study: Prospective observational cohort of 200 consecutive cases of child rape referred for assessment to a state hospital, Oct–Dec 2004

Location: KwaZulu-Natal, South Africa

Sample size: n=200 children and adolescents presenting with history of child rape; mean age 10.6 years (range, 1–17 years); 120 children eligible and offered nPEP; n=64 children not eligible due to presentation >72 hours; n=113 followed by hospital; n=7 referred to another nPEP provider

Risk: Child sexual abuse

Intervention: 2-drug regimen

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 40/113 (35.5%) followed by hospital completed 28-day course

HIV seroconversions: No seroconversions among 13/40 children returning for 3-month follow-up and 4/40 children returning at 6-month follow-up.

Conclusion: Poor nPEP adherence and return for follow-up existed; further research is needed to identify reasons for such nonadherence and identify interventions to improve adherence.

Authors, year: Du Mont et al, 2008[44]

Type of study: Retrospective analysis of data on female adolescent sexual assault survivors from the HIV PEP Project, an implementation and evaluation of a program of universal offering of nPEP to sexual assault victims of all ages in 18 hospital-based sexual treatment centers

Location: Ontario, Canada

Sample size: n=386 sexually assaulted female adolescents; mean age 16.7 years (range, 12–19 years); n=325 eligible for nPEP; 307 offered nPEP; n=131 accepted nPEP; the most common reason for declining nPEP was lack of concern about acquiring HIV; students, survivors with marked anxiety, and those encouraged by a health professional were more likely to accept PEP

Risk: Sexual assault

Intervention: 3-drug regimen; 2-pill burden

Drug regimen: Combivir and Kaletra

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 34% (44/131) completed 28-day course nPEP; 47% (61/131) adhered to day 14; the most common side effects were nausea, fatigue, vomiting, and diarrhea; survivors who were white and had known their assailant<24 hours were more likely to complete nPEP; most common reasons for stopping nPEP early: ARV side effects (73%), including most often nausea and fatigue

HIV seroconversions: Permission not obtained to provide results of HIV testing

Conclusion: Stronger health care provider recommendations needed for nPEP; need for training of health care providers to consistently offer and recommend nPEP to all those meeting established risk criteria.

Authors, year: Ellis et al, 2005[37]

Type of study: Prospective study of children presenting to hospital with history of child sexual abuse during January, 1 2004 through December 31, 2004

Location: Blantyre, Malawi

Sample size: n=64 children presented with history of sexual assault; median age 83 months (range, 22–180 months); n=17 children eligible for, offered, and accepted nPEP

Risk: Sexual assault

Intervention: 2-drug regimen

Drug regimen: AZT+3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 11/17 (65%) accepting nPEP completed 28-day course

HIV seroconversions: Among nPEP users, no seroconversions among 11 who returned after 1 month, 7 who returned after 3 months, and 2 who returned at 6 months; 1 of 4 children who did not receive nPEP was screened for HIV and was HIV+

Conclusion: The study found nPEP to be safe, acceptable, and feasible. The authors recommend routine offering of nPEP to all eligible children.

Authors, year: Fajman et al, 2006[41]

Type of study: Retrospective study of medical records of children presenting with child sexual abuse to inner-city pediatric ED in 2002

Location: Atlanta, GA

Sample size: n=227 sexually assaulted children and adolescents with adequate data; age range, 9 months–18 years; n=87 presented ≤72 hours of assault; n=5 sexually assault adolescent survivors were prescribed nPEP; being assaulted by a stranger associated with receiving nPEP (PR=11.9, 95% CI=1.4, 100.2, P=0.02).

Risk: Sexual assault

Intervention: 3-drug regimen; 2-pill burden

Drug regimen: Combivir (ZDV + 3TC) + nelfinavir

Time from exposure to nPEP: Within 72 hours

Completion of nPEP: 0 completed 28-day course

HIV seroconversions: No seroconversions reported among the 3 nPEP recipients who were tested, or among the 82 patients who presented within 72 hours but did not receive nPEP

Conclusion: nPEP for pediatric HIV exposures was underutilized in a hospital in a large urban center with high HIV prevalence and underscores the need for physician education about nPEP for children.

Authors, year: Girardet et al, 2009[35]

Type of study: Retrospective medical record review of children and adolescents presenting at a sexual abuse clinic during a 38-month period (January 2001–March 2004)

Location: Houston, Texas

Sample size: Of 4,234 cases of child or adolescent sexual assault, 1,750 (41%) were tested for HIV; n=879 aged<13 years, n=871 adolescents; n=303 were nPEP eligible; 16/303 (5%) were offered nPEP (aged 3–17 years); n=15 accepted nPEP

Risk: Sexual assault

Intervention: 2- or 3-drug regimen

Drug regimen: ZDV + 3TC (14 cases); ZDV + 3TC +LPV/r (1 case of acute genital trauma)

Time from exposure to nPEP: ≤96 hours

Completion of nPEP: Inconsistent reporting; none of the children completed follow-up; no reported significant side effects among the 9 patients reporting for at least 1 follow-up visit

HIV seroconversions: No seroconversions among 9 children who returned for ≥1 follow-up visit

Conclusion: Only 5% of those children or adolescents who were eligible for nPEP were offered nPEP. Adherence was difficult to document based on limited adherence to follow-up visits. Need for research to better define nPEP efficacy in children and adolescents.

Authors, year: Merchant et al, 2004[39]

Type of study: Retrospective medical record review of female adolescents presenting at an urban pediatric ED (January 1999 to December 2000)

Location: New York, New York

Sample size: n=25 adolescent females aged 12–19 years presenting with history of sexual assault; n=15 eligible for and offered nPEP; n=14 accepted nPEP

Risk: Sexual assault

Intervention: 1- or 3-drug regimen

Drug regimen: 1 received ZDV in 1999; 13 received 3-drug regimen, ZDV + 3TC + 3rd drug (n=12); d4T + 3TC + 3rd drug (n=1); (3rd drug was NFV [n=9] or IDV [n=4])

Time from exposure to nPEP: ≤72 hours; nPEP ordered an average of 218 minutes after patient presented to the ED; patient received drugs on average 58 minutes after nPEP was ordered

Completion of nPEP: No patients completed 28-day course

HIV seroconversions: Not reported (efficacy not studied in this study)

Conclusion: There was a significant delay in ordering nPEP and administering nPEP in the emergency room. Highlights importance of expediting nPEP in that setting.

Authors, year: Neu et al, 2007[38]

Type of study: Prospective nonrandomized observational study of children and adolescents presenting to the pediatric ED during March 1999–September 2002

Location: New York City, New York

Sample size: n=70 patients (aged 11–19 years) evaluated for sexual assault; n=33 enrolled in the study (94% female; mean age 15.3 years)

Risk: Sexual assault

Intervention: 2-drug regimen; 1-pill burden

Drug regimen: Combivir

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 8/33 (24%); return rate for follow-up visits: 1st visit, 23/33 (70%); week 2, 20/33 (60%); week 4–6, 11/33 (33%); 12 weeks, 9/33 (27%); 24 weeks, 6/33 (18%)

HIV seroconversions: No seroconversions in those presenting for follow-up at 4–6 weeks (11/33), 12 weeks (9/33), or 24 weeks (6/33)

Conclusion: Inadequate adherence to medications and follow-up were significant problems in this nPEP program for sexually assaulted children and adolescents.

Authors, year: Schremmer et al, 2005[36]

Type of study: Retrospective medical record review of children presenting for evaluation of suspected sexual abuse who were provided nPEP during February 1999–March 2001.

Location: Kansas City, Missouri

Sample size: n=2,865 evaluated for suspected sexual abuse; n=34 children and adolescents received nPEP (aged 12 weeks to 18 years, mean age 13 years); nPEP use associated with stranger assault

Risk: Sexual abuse

Intervention: 1-, 2-, and 3-drug regimens

Drug regimen: ZDV (n=1); ZDV + 3TC (n=32); ZDV+3TC+NFV (n=1)

Time from exposure to nPEP: ≤73 hours (range, 2–73 hours)

Completion of nPEP: 8/34 (24%) patients completed 28-day course

HIV seroconversions: No seroconversions among 33 patients tested at initial evaluation or among the 16 patients who had at least 1 subsequent HIV test after initial evaluation

Conclusion: Inadequate adherence to medication regimen and follow-up in child and adolescent survivors of suspected sexual abuse who received nPEP were noted.

Authors, year: Speight et al, 2006[40]

Type of study: Retrospective medical record review of children presenting with suspected childhood rape to a sexual assault care center during July 2003–March 2004

Location: Thika, Kenya

Sample size: n=48 children aged<18 years (96.8% female) presenting with suspected rape; n=33 eligible for, offered, and accepted nPEP

Risk: Sexual assault

Intervention: 2-drug regimen

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 15/33 (45%) completed 28-day course

HIV seroconversions: No seroconversions among 3 patients tested for HIV; 3 seroconversions among 15 who were not eligible for nPEP

Conclusion: Majority (86%) of children presented within the 72-hour window period. Providing post-rape care is feasible and acceptable but requires special training for counselors, and providers, including training related to pediatric dosing.

Pediatric and Adolescent Community-acquired Needlestick Injury (CA-NSI) Studies

Authors, year: de Waal et al, 2006[66]

Type of study: Case report of nPEP use among children involved in a mass needlestick injury (1999)

Location: Tygerberg, South Africa

Sample size: n=54 children involved in mass needlestick exposure from discarded needles on a soccer field; n=44 were administered nPEP

Risk: CA-NSI

Intervention: 2-drug regimen

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: ARV adherence declined from 64% at week 3 to 52% at week 4; 7 patients on nPEP experienced nausea at 3 weeks

HIV seroconversions: No seroconversions to HIV, HBV, or HCV were noted in 44 children tested at 6 months

Conclusion: Follow-up of patients after mass exposure was difficult and adherence to nPEP was poor. Fewer follow-up visits are probably adequate in a non-mobile community (might consider eliminating the 3-month follow-up visit).

Authors, year: Papenburg et al, 2008[65]

Type of study: Combination of prospective and retrospective case series describing community acquired needle stick injuries in children at 2 pediatric tertiary care teaching hospitals (1988–2006 for one hospital and 1995–2000 at another hospital)

Location: Montreal, Canada

Sample size: n=274 pediatric patients with community acquired needlestick injuries; 73% of patients sought care on day of injury; n=210 injuries occurred during an era when nPEP was available; n=87 patients offered nPEP; n=82 patients accepted nPEP

Risk: CA-NSI; blood reported on needle or syringe in 36 injuries; n=71 reported an injury that bled

Intervention: 2-drug or 3-drug regimen

Drug regimen: ZDV + 3TC (n=74); ZDV + 3TC + NFV (n=4); ZDV + 3TC + IDV (n=3); ZDV + 3TC + RTV (n=1)

Time from exposure to nPEP: Not specified

Completion of nPEP: 10/82 (12%) patients discontinued nPEP; unclear from report if remaining 72 completed the full 28-day course

HIV seroconversions: 0 HIV seroconversions occurred at 6 month follow-up visit among 189/274 (nPEP and non-nPEP) patients tested for HIV

Conclusion: There were no seroconversions for HIV, HBV, or HCV among the 274 pediatric, community-acquired needlestick injuries, adding evidence that suggests the risk of transmission of bloodborne viruses in these exposures is low.

Authors, year: Russell et al, 2002[67]

Type of study: Prospective study of children with community-acquired needlestick injuries (published 2002)

Location: Melbourne, Australia

Sample size: n=50 cases of CA-NSI; median age=6.9 years (range, 1.8–14.3 years)

Risk: CA-NSI

Intervention: No nPEP offered

Drug regimen: Not applicable

Time from exposure to nPEP: Not applicable

Completion of nPEP: Not applicable

HIV seroconversions: No seroconversions among 36 children tested for HIV, HBC, HBC

Conclusion: No seroconversions to HIV, HBV, or HCV occurred among 50 cases of CA-NSI; HBV prophylaxis and vaccination was administered and no nPEP for HIV was administered.

Authors, year: Thomas et al, 2006[64]

Type of study: Case report of CA-NSIs sustained by 21 children on primary school playground, including an HIV-infected source patient

Location: London, England

Sample size: n=20 children exposed and started on nPEP; 1 child already known to be HIV infected at baseline, not started on nPEP

Risk: CA-NSI

Intervention: 3-drug regimen

Drug regimen: ZDV + 3TC + NVP

Time from exposure to nPEP: Within 72 hours

Completion of nPEP: 10/20 (50%)

HIV seroconversions: None

Conclusion: Was logistically difficult to provide nPEP under such circumstances, however, it seemed to be effective.

Mixed Populations Studies

Authors, year: Babl et al, 2000[58]

Type of study: Retrospective medical record review of children and adolescents presenting with CA-NSI in to the pediatric emergency room of an urban hospital during June 1997–June 1998

Location: Boston, Massachusetts

Sample size: n=10 pediatric and adolescent patients offered nPEP; n=8 started on nPEP

Risk: Sexual assault (n=6); CA-NSI (n=4)

Intervention: 3-drug regimens

Drug regimen: ZDV + 3TC+ Indinavir (n=7); ZDV + 3TC+ NFV (n=1)

Time from exposure to nPEP:

Completion of nPEP: 2/8 (25%) completed 28-day course; financial concerns, side effects, additional psychiatric and substance abuse issues, degree of parental involvement influenced adherence to nPEP and follow-up

HIV seroconversions: No seroconversions among 5 tested at 4 to 28 weeks.

Conclusion: HIV nPEP presented medical and management challenges and requires coordinated effort. Need for written protocol, coordinated approach, and national guidelines.

Authors, year: Beymer et al, 2014[61]

Type of study: Retrospective medical record review of clients receiving PEP services at LGBT community-based clinic (May 2011–December 2012)

Location: Los Angeles

Sample size: n=649 nPEP clients (n=529 [81.5%] first PEP use, n=120 [18.5%] PEP use 1–5 times previous to current nPEP initiation); whites, Hispanics, and blacks made up 42.5%, 35.4%, and 8.8% of nPEP users, and 30.4%, 42.4%, and 16.7% of HIV-infected persons, respectively

Risk: Gay/homosexual 75.5%, bisexual 11.9%, heterosexual 10.6%, other 1.9%

Intervention: 2-drug regimen

Drug regimen: TDF/FTC

Time from exposure to nPEP: ≤72 hours; mean time from exposure to first PEP medication dose 38.5 hours (SD=19 h)

Completion of nPEP: 93% self-reported taking all 4 pills in the previous 4-day medication recall period at 2 weeks after nPEP initiation

HIV seroconversions: 7 seroconversions occurred during the 6-month study period after nPEP initiation (including the 5 months after completing nPEP; exact timing not described)

Conclusion: 18.5% repeat nPEP users may benefit from PrEP; racial/ethnic inequities found in nPEP use compared with corresponding HIV prevalence deserves attention.

Authors, year: Bogoch et al, 2014[59]

Type of study: Prospective longitudinal study of referrals to nPEP programs in 2 emergency rooms and 2 academic medical centers

Location: Boston, MA

Sample size: n=180 persons referred for nPEP; median age 28 years (interquartile range, 23–35 years); 65.6% women; n=98 (54.4%) attended first nPEP visit

Risk: Sexual (57.2%), 72% nonconsensual, 1% MSM; nonsexual (42.8%), 17.8% injecting-drug use, 40% accidental needlestick injuries, 42.2% accidental mucous membrane or non-needle percutaneous exposures

Intervention: 3-drug regimen

Drug regimen: First line regimen: co-formulated TDF and FTC (Truvada) and LPV/r (Kaletra); RAL was substituted for LPV/r with drug interactions or side effects preventing adherence

Time from exposure to nPEP: Not reported

Completion of nPEP: 43/177 (46%) patients had documented completion of a 28-day course of nPEP; women were less likely to complete a 28-day course of nPEP

HIV seroconversions: Not reported

Conclusion: There were significant attrition rates between the emergency department and nPEP follow-up clinic. Older patients and persons without insurance were significantly less likely to attend initial clinic for nPEP care after presenting to the emergency department. Individuals with exposure to a known HIV-positive source individual were more likely to attend their initial clinic appointment. Women accounted for the majority of nonconsensual sexual exposures and were less likely to have documented completion of their 28-day nPEP regimen.

Authors, year: Chan et al, 2013[52]

Type of study: Retrospective cohort study with medical record review at large urban hospital emergency room, January 1, 2008–December 31, 2010

Location: Toronto, Canada

Sample size: n=241 patients

Risk: All were sexual exposures; MSM 76.8%, heterosexual 23.2%, non-consensual 5.0% of 236 with documentation about whether sex was consensual; HIV-positive source n=102

Intervention: 2-drug regimen (for lower risk exposures), 3-drug regimen (for higher risk exposures)

Drug regimen: Not specified

Time from exposure to nPEP: ≤72 hours; among 205 with known timing of exposure: <24 hr, 70 (34.1%); 24–48 hr, 68 (33.2%); 48–72 hr, 28 (13.7%); >72 hr, 7 (3.4%); not documented, 32 (15.6%)

Completion of nPEP: Of 205 patients given nPEP, n=71 (34.6%) completed a 28-day course; n=20 (9.8%) stopped medications early due to patient preference, cost, low HIV risk, source patient tested HIV negative; n=114 (55.6%) unknown completion status; n=55 with adverse effects, diarrhea (n=20), nonspecific gastrointestinal upset (n=14), nausea (n=13)

HIV seroconversions: Two patients who initially tested HIV negative at baseline subsequently tested HIV-positive at 3-month and 6-month visits; data regarding ongoing sexual exposure was incomplete

Conclusion: While it was encouraging that 92.6% of patients presented within the 72-hour window period, only 34.6% were known to have completed the full 28-day course. It is unclear whether the 2 HIV seroconversions that occurred during the 3-month and 6-month follow-up visits were nPEP failures as sexual histories were incomplete during follow-up.

Authors, year: Diaz-Brito et al, 2012[53]

Type of study: Open label randomized multicenter clinical trial comparing 2 nPEP regimens in patients presenting to emergency rooms in 6 urban hospitals

Location: Barcelona, Spain

Sample size: n=255 patients presenting for nPEP evaluation randomized into ZDV/3TC + LPV/r twice daily arm (n=131) or ZDV/3TC + atazanavir (n=124)

Risk: n=200; nonoccupational n=170 (85%); sexual n=156 (78%); occupational n=30 (1%)

Intervention: 3-drug regimen

Drug regimen: ZDV/3TC + LPV/r or ZDV/3TC + atazanavir

Time from exposure to nPEP: Median interval between exposure and presentation=18h (IQR 5–32); nonoccupational (median=20 hours); occupational (median=5 hours)

Completion of nPEP: 64% completed 28-day course in both arms; 92% of patients reported taking >90% of scheduled doses (without difference between arms); adverse events reported in 46% of patients (49% LPV/r arm and 43% atazanavir arm); gastrointestinal problems more common in LPV/r arm

HIV seroconversions: 0

Conclusion: Rate of completion was similar for both arms; almost 50% of patients of both arms suffered side effects. Strategies to improve adherence are needed.

Authors, year: Fletcher et al, 2013[63]

Type of study: Prospective cohort study

Location: Los Angeles, California

Sample size: n=35 patients; gay n=30; not gay=5; mean age=34.1 years (SD 7.4)

Risk: Not clearly defined; however, participants reported mean of 11.9 (SD 26.5) episodes of unprotected anal intercourse in past 6 months

Intervention: 2-drug regimen

Drug regimen: TDF + FTC (Truvada)

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 25/35 (71.4%) completed the 28-day course; 48.6% took all 28 doses; 14.3% took >90% of doses; at baseline, higher number of lifetime STDs and recent episodes of unprotected anal intercourse were associated with reductions in medication adherence

HIV seroconversions: 1 (participant reported nonadherence to nPEP and multiple subsequent sexual exposures)

Conclusion: There was a significant indirect association between sexual risk taking and nPEP adherence. Interventions to reduce sexual risk taking will reduce risk for HIV acquisition and may play a role in improving nPEP adherence.

Authors, year: Gulholm et al, 2013[54]

Type of study: Retrospective medical record review at urban hospital sexual health clinic (1/2008–12/2011)

Location: Sydney, Australia

Sample size: n=282 patients on 319 occasions presented for nPEP; n=262 (94.3%) male

Risk: n=260 (99.2%) participants had homosexual exposure; of 319 presentations, 203 (63.6%) receptive unprotected anal intercourse, 87 (27.4%) insertive anal intercourse, 12 (3.8%) receptive vaginal intercourse, 5 (1.6%) penile-vaginal sexual assault, 5 (1.6%) receptive fellatio, 5 (1.6%) needlestick injuries, 4 (1.3%) needle-sharing episodes

Intervention: 2-drug or 3-drug regimen

Drug regimen: Mainly TDF/FTC-containing regimens; TDF + FTC (n=136 [42.6%]), TDF + FTC + d4T (n=149 [46.7%])

Time from exposure to nPEP: ≤72 hours; <4 hours (16 [5.1%]), 4–12 hours (59 [19.0%]), 12–24 hours (82 [26.5%]), 24–48 hours (96 [31.0%]), 48–72 hours (57 [18.4%])

Completion of nPEP: 228/319 (71/%) completed nPEP; completion associated with reporting AEs and changing the nPEP regimen; adverse events associated with being prescribed a regimen other than TDF/FTC, younger age, earlier year of nPEP prescription, and changing the nPEP regimen

HIV seroconversions: 2 seroconversions more than 6 months after NPEP due to ongoing high-risk behavior

Conclusion: nPEP was appropriately targeted to highest risk patients. HIV seroconversions due to ongoing high-risk sexual behavior highlight importance of integrating counseling regarding safer sexual behaviors as an integral component of nPEP care.

Authors, year: Jain et al, 2015[60]

Type of study: Retrospective longitudinal study of electronic medical records of nPEP users (1999–2013)

Location: Boston, Massachusetts

Sample size: n=894 patients; n=1,244 nPEP courses; mean age at PEP enrollment=33.9 years

Risk: MSM=788; heterosexual=91; sexual assault=66; transgender=15; injection drug use=14; sexual exposure (non-assault)=1,152

Intervention: n=927 TDF-based treatment regimen; N=592 3-drug regimen

Drug regimen: Either an AZT/3TC or TDF/FTC backbone with or without a third drug.

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 85.7% completion rate overall (463 of 540 with documented completion status); reasons for discontinuing: medication intolerance (48.1%) due to nausea (43.2%), diarrhea (13.5%), rash (13.5%), HIV negative partner (9.1%); increased completion rates associated with having HIV-infected partner or fewer drugs in regimen (2 vs.3)

HIV seroconversions: Not reported

Conclusion: nPEP use increased over time. nPEP users demonstrated recurrent high-risk behavior. A defined group of nPEP users may benefit from earlier, targeted HIV risk-reduction and PrEP counseling.

Authors, year: Mayer et al, 2008[56]

Type of study: Two phase 4 studies of TDF-containing regimens compared to historical controls who took ZDV-containing regimens

Location: Boston, Massachusetts

Sample size: n=353 enrollees; n=44 (TDF/FTC arm); n=68 (TDF/3TC arm); control arms: n=122 ZDV/3TC arm, n=119 ZDV/3TC + 3rd drug arm

Risk: Sexual exposure; TDF/FTC arm, n=41 (93.2%) male (MSM/bisexual), n=41 male (100%); TDF/3TC arm, n=66 (97.1 %) male, n=56 (82.4% MSM/bisexual); ZDV/3TC arm, n=98 (80.3%) male; ZDV/3TC + 3rd drug arm, n=88 (73.9%)

Intervention: 3 separate 2-drug regimens and one 3-drug regimen; 1-, 2-, or 3-pill burden

Drug regimen: TDF + 3TC, TDF + FTC, or ZDV + 3TC (with or w/o a PI)

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 42–87.5% completed nPEP (highest completion in TDF regimens): 72.7% (n=32 TDF/FTV arm), 87.5% (n=63 TDF/3TC arm), 42.1% (n=53 ZDV/3TC arm), 38.8% (n=50 ZDV/3TC + 3rd drug arm [3rd drug was mainly PI])

HIV seroconversions: In TDF arms, n=0 seroconversions; in AZT arms, n=3 (during or shortly after their course of nPEP); Note: Level of adherence in seroconverters not described.

Conclusion: Participants taking TDF-containing regimens for nPEP demonstrated greater adherence and tolerability, with milder side effects than those taking ZDV-containing regimens.

Authors, year: Mayer et al, 2012[57]

Type of study: Evaluation of a novel 3-drug nPEP regimen

Location: Boston, MA

Sample size: TDF-FTC-RAL arm (n=100); control arms: TDF/FTV arm, n=44; AZT/3TC +3rd drug arm, n=119; overall age range, 18–61 years; males (73.9%–100%—all arms); MSM/bisexual (70.5%–71.5% in TDF arms)

Risk: Sexual exposure to HIV-infected partner or partner of unknown HIV status

Intervention: 3-drug regimen; 2-pill burden

Drug regimen: RAL + fixed dose combination TDF and FTC (Truvada)

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: 57% (n=57) completed TDF-FTC-RAL arm (an additional 27% completed a modified regimen.); 72.7% (n=32) completed TDF/FTV arm; 38.8% (n=46) completed AZT/3TC arm

HIV seroconversions: 0

Conclusion: Tolerability to the 3-drug regimen, with integrase inhibitor, RAL, was high. The most common side effects were nausea and vomiting, diarrhea, abdominal discomfort, headache, and fatigue.

Authors, year: McDougal et al, 2014[62]

Type of study: Retrospective medical record abstraction of patients attending a publicly funded HIV clinic between 2000 and 2010

Location: Seattle, Washington

Sample size: 360 evaluated for nPEP; 324 prescribed nPEP; median age 30 years (range, 14 years–68 years)

Risk: Among patients evaluated for nPEP: sexual exposures (928%), MSM (59%), sexual assault (22%)

Intervention: 66% (n=214) 3-drug regimen

Drug regimen:

Time from exposure to nPEP: 334/260 (93%) initiated ≤72 hours, 177/360 (49%) within 24 hours

Completion of nPEP: 287/324 (89%) completed nPEP

HIV seroconversions: n=4; 2 tested positive at 2 and 5 months; 1 tested negative at baseline and 11 days and positive at 5 months; 1 tested positive at 12 months after nPEP initiation; adherence to nPEP and history of ongoing sexual exposures not described

Conclusion: Must increase education and promotion of HIV prevention, including nPEP for populations who would benefit most. Established nPEP service sites may have added benefit of also serving as locations for HIV case-finding and PrEP referrals.

Authors, year: Olowookere et al, 2010[51]

Type of study: Retrospective medical record abstraction of clients presenting for HIV nPEP at an antiretroviral therapy clinic during January 2005–December 2006

Location: Ibadan, Nigeria

Sample size: n=48 clients received nPEP; mean age 27.9 years ± 12.3 years (n=6, <15 years); about 1/3 were children and adolescents

Risk: Nonoccupational exposures: sexual assault (50%); occupational exposures: needlesticks (25%), blood splash into mucous membranes (25%)

Intervention: 3-drug regimen

Drug regimen: Either ZDV + 3TC + 3rd drug or D4T + 3TC + 3rd drug; 3rd drug=EFV, IDV or LPV/r

Time from exposure to nPEP: Not reported

Completion of nPEP: 38/48 (79%) completed therapy

HIV seroconversions: No seroconversions among 40 clients at 6 months of follow-up

Conclusion: 24% of clients receiving nPEP could not complete therapy due to side effects.

Authors, year: Pierce et al, 2011[45]

Type of study: Data linkage study using an nPEP service database and an HIV surveillance registry

Location: Australia

Sample size: n=1,420 male nPEP recipients; age range, 14–78 years; median=34.5 years

Risk: Indirect data suggest most participants presenting for NPEP are MSM, but risk behaviors were not collected for these participants

Intervention: Number of drugs in nPEP regimen not reported.

Drug regimen: Not reported

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: Not reported

HIV seroconversions: n=3 nPEP related failures; n=34 additional seroconversions >6 months after nPEP initiation and deemed related to ongoing risk behavior

Conclusion: Frequency of nPEP use was not associated with risk of HIV seroconversion. Note: Data on nPEP adherence and completion were not available, but may have provided an explanation for drug failure.

Authors, year: Rey et al, 2008[46]

Type of study: Retrospective medical record abstraction of all consultations for nPEP in three consultation centers January 2001–December 2002

Location: Southeastern France

Sample size: n=910 exposures; age range, 15–18 yr (5.9%), 19–35 yr (68.6%), 36–50 yr (21.4%), >50 yr (4.1%); men=60.4%; female=39.2%; transsexual=0.3%; n=800 given initial nPEP prescription; n=776 accepted nPEP; n=527 received remaining nPEP prescription to complete 28-day course

Risk: n=910 sexual exposures, including 108 sexual assaults, 220 homosexual contacts among men

Intervention: 2- or 3-drug regimen

Drug regimen: Not reported

Time from exposure to nPEP: nPEP given before and after the 72 hour window period

Completion of nPEP: 355/776 (44%) who accepted nPEP completed 28-day course

HIV seroconversions: 1 seroconversion occurred in a patient after completing nPEP but who presented >72 hours after a high-risk exposure (not considered an nPEP failure)

Conclusion: Follow-up rates were poor; strategies need to improve follow-up, including a tracking process and psychosocial support for youngest patients and survivors of sexual assault.

Authors, year: Shoptaw et al, 2008[55]

Type of study: Biobehavioral HIV prevention intervention

Location: Los Angeles

Sample size: n=100 enrollees

Risk: High-risk sexual or drug-related exposure; n=45 drug use, n=1 injection drug use, n=63 MSM, n=9 bisexual, n=9 heterosexual; mean age 31.8 years

Intervention: 2-drug regimen; 1-pill burden

Drug regimen: ZDV + 3TC

Time from exposure to nPEP: ≤72 hours

Completion of nPEP: n=84 individuals received the full 28-day supply of study drug; 63/84 (75%) completed nPEP

HIV seroconversions: 0

Conclusion: nPEP provision for persons at high risk for HIV is feasible and safe at the community level. The most common adverse events were fatigue, nausea, headache, and gastrointestinal complaints.

Authors, year: Siika et al, 2009[47]

Type of study: Retrospective cohort study of electronic medical records of patients enrolled for HIV nonoccupational and occupational PEP during November 2001–December 2006 (Note: Only results for nPEP patients summarized in this table)

Location: Eldoret, Kenya

Sample size: n=355 nPEP exposures among children, adolescents, and adults; 100% accepted nPEP; n=296 advised to continue nPEP after testing HIV negative at baseline

Risk: Sexual assault (n=292 [82%]; female adult [n=189], female child [n=91], male child [n=15]); unprotected consensual sex, condom malfunction, human bites, exposure to body fluids of individuals suspected to be HIV infected, and barber cuts (n=63 [18%])

Intervention: 3-drug regimen; 2- or 3-pill burden

Drug regimen: D4T + 3TC + NVP; ZDV + 3TC + LPV/r (Note: Authors do not distinguish between ARVs used for nPEP or oPEP)

Time from exposure to nPEP: Median time=19 hours (range, 1–672 hours; 86% <72 hours)

Completion of nPEP: 104/296 (35%) completed nPEP. No statistically significant difference in reported side effects between NVP arm (21%) and LPR/r arm (14%) (P=0.44). No difference in completion rates for two arms (P=0.91). 1 death related to ARV-associated acute hepatitis associated with NVP arm.

HIV seroconversions: 1 HIV seroconversion at 6 weeks after nPEP initiation using RNA PCR test among 129 patients; seroconversion occurred in sexually assaulted child who presented ≤4 hours of assault and completed nPEP. HIV ELISA tests were negative in 87 patients; however, child who seroconverted did not undergo ELISA testing as well.

Conclusion: It is feasible to provide nPEP and oPEP in resource-constrained settings. Lack of HIV testing, delayed presentation, ARV discontinuation, and loss to follow-up are challenges in Western Kenya. Centralization of PEP services may improve coordination and supervision.

Authors, year: Tissot et al, 2010[48]

Type of study: Retrospective medical record abstraction of nPEP administrations during 1998–2007

Location: Lausanne, Switzerland

Sample size: n=1,233 consultations for potential HIV exposure; n=910 exposures among 867 persons included in final analysis; n=830 individuals requested nPEP at least once; n=710 initiated nPEP; 64% male, median age 30 years (range, 14–87 years)

Risk: 58%=heterosexual; 15%=homosexual; 6%=sexual assault; 20%=nonsexual (mainly CA-NSI or sharing of injection drug equipment)

Intervention: 3-drug regimen

Drug regimen: Mainly ZDV + 3TC + NFV (n=548, 77%) or ZDV + 3TC + LPV/r (n=108, 15%)

Time from exposure to nPEP: 60% sought care ≤24 hours after exposure and 82% sought care ≤48 hours

Completion of nPEP: 423/710 (60%) completed 28-day course; 396/620 (64%) for which data were available, reported side effects (mainly gastrointestinal disturbance and fatigue)

HIV seroconversions: 2 seroconversions occurred during follow-up, not attributable to nPEP failures

Conclusion: HIV testing in source persons avoided nPEP in 31% of exposures.

Authors, year: Tosini et al, 2010[49]

Type of study: Multi-site prospective study to evaluate the tolerability of nPEP with TDF/FTC +LPV/r

Location: France

Sample size: n=249 men and women; mean age 31.5 years; n=166 completed 28 days of PEP (tolerability good in 58%)

Risk: Nonoccupational exposures: sexual intercourse n=204 (82%), other n=5 (2%); occupational exposures (n=40)

Intervention: One 3-drug regimen; 2-pill burden

Drug regimen: TDF + FTC + LPV/r vs. historical controls taking ZDV containing regimens or TDF + ATV

Time from exposure to nPEP: ≤48 hours

Completion of nPEP: 166/188 (88%)

HIV seroconversions: No HIV seroconversions were recorded during the study

Conclusion: The TDF/FTC + LPV/r regimen proved easy to use, well-tolerated, and had less participants to discontinue medications secondary to adverse effects when compared with historical controls. The authors recommend this regimen as standard of care for HIV nPEP. Among those with ≥1 side effect, 78% diarrhea, 78% asthenia, 59% nausea and/or vomiting.

Authors, year: Wong et al, 2010[50]

Type of study: Observational study of nPEP use following nPEP protocol and guidelines development in one Canada province

Location: Alberta, Canada

Sample size: n=174 persons received nPEP (135 females, 39 males); median age 24 years (range 4–69 years)

Risk: Sexual assault (68%, n=118), percutaneous (21%, n=36), consensual sex (7%, n=12), mucosal (3%, n=5), other (0.6%, n=1), not documented (1%, n=2)

Intervention: Primarily 2 and 3-drug regimens, one 4-drug regimen

Drug regimen: Not explicitly reported; most regimens included ZDV

Time from exposure to nPEP: 86% of cases ≤48 hours

Completion of nPEP: 86/174 (49%)

HIV seroconversions: 0 of 143

Conclusion: The majority of nPEP cases were sexual assaults in young women. No seroconversions were observed, however, lack of follow-up and early discontinuation of medication were problematic. NPEP programs need to better address adherence and follow-up.

Blood Transfusion Study

Authors, year: Al-Hajjar et al, 2014[71]

Type of study: Case report of nPEP use following inadvertent HIV-infected blood transfusion

Location: Riyadh, Saudi Arabia

Sample size: One 12 year old girl with sickle cell disease

Risk: Child was inadvertently transfused with large volume of HIV-infected packed red blood cells

Intervention: 4-drug regimen

Drug regimen: TDF, FTC, DRV/r and RAL (DRV/r subsequently changed to LPV)

Time from exposure to nPEP: At 24 hours after transfusion

Completion of nPEP: Completed 13 weeks of ARV PEP

HIV seroconversions: Patient did not seroconvert (negative for HIV-1 DNA and plasma HIV-1 RNA by PCR through 8 months following exposure)

Conclusion: Authors report successful use of combination ART nPEP after a large volume transfusion of HIV-contaminated blood despite detection initially of HIV antibodies immediately after the transfusion. The fact that antibodies disappeared after nPEP initiation cautions against not starting or stopping nPEP in patients with detectable antibodies immediately after a contaminated blood transfusion.

Abbreviations

3TC, lamivudine; ATV, atazanavir; AZT, zidovudine; CA-NSI, community-acquired needlestick injury; d4T, stavudine; DRV/r, darunavir + ritonavir; ED, emergency department; ELISA, enzyme-linked immunosorbent assay; EFV, efavirenz; FTC, emtricitabine; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IDV, indinavir; LPV, lopinavir; LPV/r, lopinavir/ritonavir; MSM, men who have sex with men; NFV, nelfinavir; nPEP, nonoccupational postexposure prophylaxis; NVP, nevirapine; oPEP, occupational postexposure prophylaxis; PEP, postexposure prophylaxis; PI, protease inhibitor; PrEP, preexposure prophylaxis; RAL, raltegravir; RNA PCR, ribonucleic acid polymerase chain reaction; RPV, rilpivirine; SD, standard deviation; TDF, tenofovir disoproxil fumarate; ZDV, zidovudine.

Trade-named Drug Compositions

Combivir, ZDV+3TC; Kaletra, LPV/r (lopinavir + ritonavir); Truvada, TDF + FTC.

3280

Appendix 4

Consideration of Other Alternative HIV nPEP Antiretroviral Regimens[a]

Create a combination regimen alternative to those in Table 5: May combine 1 drug or drug pair from Column A with 1 pair of nucleoside/nucleotide reverse transcriptase inhibitors from Column B.

Or

Use an existing fixed-dose combination alternative to those in Table 5.

Prescribers unfamiliar with these medications should consult physicians familiar with the agents and their toxicities.

Column A	Column B
Raltegravir Darunavir + ritonavir Etravirine Rilpivirine Atazanavir + ritonavir Lopinavir/ritonavir Dolutegravir	Tenofovir DF+ emtricitabine Tenofovir DF + lamivudine Zidovudine + lamivudine Zidovudine + emtricitabine

Fixed-dose combinations

The fixed-dose combinations Stribild (elvitegravir, cobicistat, tenofovir DF, emtricitabine) and Complera (rilpivirine, tenofovir DF, and emtricitabine) are complete regimens and no additional antiretrovirals are needed.

ALTERNATIVE ANTIRETROVIRAL MEDICATIONS FOR USE AS nPEP ONLY WITH EXPERT CONSULTATION
Efavirenz
Enfuvirtide
Fosamprenavir
Maraviroc
Saquinavir
Stavudine
ANTIRETROVIRAL MEDICATIONS GENERALLY NOT RECOMMENDED FOR USE AS nPEP
Didanosine
Nelfinavir
Tipranavir
Abacavir
ANTIRETROVIRAL MEDICATIONS CONTRAINDICATED AS nPEP
Nevirapine
Efavirenz (not for pregnant women)
Tenofovir (not for persons with eCrCl < 60 ml/min)

Abbreviations: DF, disoproxil fumarate; eCrCl, estimated creatinine clearance; nPEP, nonoccupational postexposure prophylaxis; TM, trademark.

[a] These antiretrovirals can be considered for use in regimens alternative to those in Table 5. For detailed information on each drug, please refer to individual drug package inserts available at: AIDSInfo Drugs Database at: http://aidsinfo.nih.gov/drugs. For consultation or assistance with HIV nPEP, contact PEPline (telephone 888-448-4911; internet site: http://www.nccc.ucsf.edu/about_nccc/pepline/).

29

30

31